

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

UNITED STATES OF AMERICA, Case No. 1:10-cr-0150-SO
Cleveland, Ohio
Plaintiff, Wednesday, October 10, 2012
Thursday, October 11, 2012
VS.

AUDREY BARBARA ROVEDO,
VINESH DARJI,
TERENCE SASAKI,

Defendants.

TRANSCRIPT OF **TESTIMONY OF CARMEN CATIZONE** FROM
JURY TRIAL BEFORE THE HONORABLE SOLOMON OLIVER, JR.,
CHIEF UNITED STATES DISTRICT JUDGE

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Catizone - Direct (By Mr. Feran)

1 MORNING SESSION, WEDNESDAY, OCTOBER 10, 2012

2 * * * * *

3 THE COURT: Call your next witness.

4 MR. FERAN: Your Honor, we would call Carmen

14:19:50 5 Catizone.

6 THE COURT: Come right ahead to the witness
7 stand you see on my left, and as soon as you step up there,
8 before you take your seat, my deputy will swear you in.

9 (The witness is sworn.)

14:20:51 10 THE COURT: Mr. Feran.

11 MR. FERAN: Thank you, Your Honor.

12 DIRECT EXAMINATION OF CARMEN CATIZONE

13 BY MR. FERAN:

14 **Q.** Good afternoon, sir.

14:20:56 15 **A.** Good afternoon.

16 **Q.** I would like you to begin by stating your full name,
17 and spelling your last name for the court reporter.

18 **A.** Carmen Catizone, C-A-T-I-Z-O-N-E.

19 **Q.** It is pronounced "Catizone"?

14:21:12 20 **A.** Yes. Yes, sir.

21 **Q.** Mr. Catizone, what is your current occupation?

22 **A.** I'm a pharmacist, as well as executive director of the
23 National Association of Boards of Pharmacy.

24 **Q.** How long, sir, have you been a pharmacist?

14:21:27 25 **A.** Since 1983.

Catizone - Direct (By Mr. Feran)

1 Q. And how long have you been the executive director of
2 the National Association of Boards of Pharmacy?

3 A. I joined the organization in 1985 and have been
4 executive director since 1988.

14:21:40 5 Q. And, sir, what are your duties as the executive
6 director?

7 A. I oversee the staff and implement policies that are
8 directed by the individual state Boards of Pharmacy.

9 Q. How is this position selected, sir?

14:21:57 10 A. There's a national search that was conducted, and
11 candidates were then screened and qualified, and I was
12 selected from that screening process.

13 Q. The National Association of Boards of Pharmacy, this
14 is known by the acronym NABP; is that correct?

14:22:13 15 A. Yes, sir.

16 Q. All right, sir. So we're not here all night, I'm
17 going to refer to this by NABP if that's okay with you.

18 A. Sure.

19 Q. Prior to becoming executive director of NABP did you
14:22:24 20 have any other positions at the organization?

21 A. When I first joined them I was the test and
22 measurement director, so I oversaw all of the competency
23 programs, the national licensure exam that all the states
24 require, as well as the state law exams that 47 states
14:22:41 25 require.

Catizone - Direct (By Mr. Feran)

1 **Q.** Sir, how big is your organization?

2 **A.** It consists of the 50 state Boards of Pharmacy, the
3 provinces of Canada, the states of Australia, New Zealand,
4 and South Africa.

14:22:55 5 **Q.** And what does your organization do, sir?

6 **A.** We help the states protect the public health.

7 **Q.** Are individual pharmacists members of your
8 organization?

9 **A.** Pharmacists, pharmaceutical companies, pharmacies, are
14:23:10 10 not members of our association. Only state agencies that
11 have the legal authority to regulate pharmacies and
12 pharmacists and technicians can be members of our
13 association.

14 **Q.** So for example, Mr. Catizone, some of your members
14:23:25 15 would be, for example?

16 **A.** The Ohio State Board of Pharmacy, the Illinois Board
17 of Pharmacy. All of the state agencies that regulate
18 pharmacy.

19 **Q.** Does your organization have a lobbying component to
14:23:36 20 it, sir?

21 **A.** No, sir. Based upon our status with the IRS we're
22 prevented from lobbying, and all we can do are charitable
23 and educational activities.

24 **Q.** Mr. Catizone, I would like to talk, if we could, about
14:23:51 25 your educational background. If we could focus on that for

Catizone - Direct (By Mr. Feran)

1 a minute, sir. Could you please describe for the Ladies and
2 Gentlemen of the Jury briefly your education?

3 **A.** I received my bachelor of science in pharmacy from the
4 University of Illinois, and my master's of science and
14:24:07 5 pharmacy administration also from the University of
6 Illinois.

7 **Q.** Are you a registered pharmacist, sir?

8 **A.** Yes, sir, in Illinois.

9 **Q.** In the state of Illinois. Tell us about your

14:24:18 10 professional experience after graduating from pharmacy
11 school.

12 **A.** I practiced for 14 years as a pharmacist in a large
13 chain as well as in a hospital, and also practiced in a
14 nursing home facility, and while in graduate school became
14:24:37 15 involved in studies with the Food and Drug Administration
16 and other research projects.

17 **Q.** And what area of the country did this take place, sir?

18 **A.** In the midwest, the Chicago area.

19 **Q.** Where are you from, sir, where is your hometown?

14:24:51 20 **A.** Chicago.

21 **Q.** In addition to your practice -- how long did you
22 practice, sir, in the community and hospitals and
23 institutional settings?

24 **A.** 14 years.

14:24:59 25 **Q.** In addition to your educational background,

Catizone - Direct (By Mr. Feran)

1 Mr. Catizone, can we talk about, are you the recipient of
2 any honors or awards?

3 **A.** I've been recognized by the commissioner of the Food
4 and Drug Administration on two occasions, received a special
14:25:13 5 citation from the District of Columbia, and then various
6 awards from the college from which I graduated, as well as
7 professional associations for pharmacist of the year.

8 **Q.** Mr. Catizone, through your training and experience,
9 sir, have you developed a particular expertise in the areas
14:25:30 10 of pharmacies operating on the Internet?

11 **A.** Yes, sir.

12 **Q.** Can you tell us about them, Mr. Catizone?

13 **A.** Sure. I became involved in this area in 1997, when we
14 became aware of entities trying to sell prescription drugs
14:25:44 15 on the Internet without a prescription. We then developed
16 an accreditation program, and since 1997 we've been actively
17 involved in researching, helping the states regulate
18 Internet pharmacies, educating the public about what
19 pharmacies they should utilize, and educating legislators
14:26:05 20 and states about how best to regulate Internet pharmacies.

21 **Q.** When you say we, Mr. Catizone, who are you referring
22 to?

23 **A.** Myself and NABP, the organization that I serve.

24 **Q.** And if you could, sir, describe the functions of the
14:26:17 25 NABP more.

Catizone - Direct (By Mr. Feran)

1 **A.** We have three primary functions. One is competence
2 assessment, which means we prepare the licensure exams that
3 the states require to determine whether or not pharmacists
4 are competent to practice.

14:26:32 5 We also maintain a licensure transfer program for
6 pharmacists for the states, so that every pharmacist who
7 wants to transfer from one state to another utilizes that
8 system. We do all of the disciplinary clearing for the
9 states and submit that information so the states can make a
14:26:50 10 decision, and then we have accreditation programs for
11 wholesalers, pharmacies, and Internet pharmacies.

12 We've accredited over 30,000 retail pharmacies, over
13 600 wholesale distributors, and about half -- about 50 or so
14 Internet pharmacies, and advertisers on Google and
14:27:09 15 Microsoft.

16 **Q.** You stated that this research that you conducted,
17 Mr. Catizone, began in 1997?

18 **A.** Yes, sir.

19 **Q.** And is it continuing, sir?

14:27:16 20 **A.** Yes, sir.

21 **Q.** And can you very briefly, sir, explain the researching
22 of these Internet pharmacies?

23 **A.** What we do is we through our accreditation program we
24 actually visit pharmacies, inspect their policies and
14:27:34 25 procedures, and inspect those pharmacies to make sure they

Catizone - Direct (By Mr. Feran)

1 are in compliance with state and federal laws and the
2 standards we've developed.

3 We also actively search the Internet, and to date
4 we've reviewed over 9,000 Internet sites, and of those 9,000
14:27:48 5 sites we have found that 97 percent of those sites are
6 operating illegally or fraudulently.

7 **Q.** Has your organization, NABP, come out with a general
8 position statement with regard to dispensing and prescribing
9 over the Internet, sir?

14:28:05 10 **A.** Yes, sir.

11 **Q.** Can you tell us about that?

12 **A.** The position is quite simply that an Internet pharmacy
13 is held to the same laws, regulations, and standards as a
14 traditional brick and mortar pharmacy, and that Internet
14:28:19 15 pharmacy has to insure that there's a valid prescription,
16 that the prescription is appropriate for the patient, and
17 that there's no fraud occurring, before that pharmacy can
18 dispense that prescription.

19 **Q.** Mr. Catizone, has NABP come out with a recent
14:28:35 20 statement regarding Internet pharmacies?

21 **A.** Yes. Continuously we issue statements about Internet
22 pharmacies.

23 **Q.** And was there a recent statement made regarding
24 Internet pharmacies, sir?

14:28:45 25 **A.** I'm sorry --

Catizone - Direct (By Mr. Feran)

1 **Q.** I'll strike that. Sir, are you familiar with the
2 Controlled Substance Act?

3 **A.** Yes.

4 **Q.** And can you tell us how you're familiar with that?

14:28:58 5 **A.** As a pharmacist and as a student becoming a pharmacist
6 you are taught pharmacy law throughout the program, and the
7 main tenets of pharmacy law are the federal laws, which
8 consist of the Controlled Substance Act and the Food, Drug,
9 and Cosmetic Act, as well as state laws and regulations
14:29:17 10 where you may be practicing. And those courses, I said, are
11 throughout the curriculum, as well as special courses to
12 pharmacy laws that every pharmacist must take.

13 The pharmacist must also pass a state law exam in
14 every state in which they want to practice, and they must
14:29:35 15 maintain their continuing education in both the clinical
16 aspects of pharmacy practice as well as pharmacy law.

17 **Q.** So you studied this in pharmacy school, sir?

18 **A.** Yes, sir.

19 **Q.** Are you familiar with the term CLE?

14:29:50 20 **A.** Yes.

21 **Q.** Continue Legal Education -- Continuing Pharmacy
22 Education?

23 **A.** CPE.

24 **Q.** Can you tell us what that consists of?

14:29:59 25 **A.** Sure. Every state requires Continuing Pharmacy

Catizone - Direct (By Mr. Feran)

1 Education. Every pharmacist must complete a number of hours
2 of continuing education in order to renew their license.

3 **Q.** You talked about the Controlled Substance Act. Can
4 you define, Mr. Catizone, what a controlled substance is and
14:30:15 5 what a noncontrolled substance is?

6 **A.** Yes. There are two categories of drugs, there are
7 prescription drugs and nonprescription drugs or
8 over-the-counter drugs. Within the prescription drug class
9 there's a special class of drugs called controlled
14:30:31 10 substances. And because these drugs have a high tendency to
11 cause addiction, abuse, and harm, they are regulated
12 differently and more stringently than just a prescription
13 drug.

14 And within the controlled substance category are five
14:30:48 15 different classes of drugs: Schedule I has no medical value
16 and is the most dangerous of the schedules, and that would
17 include products like heroin.

18 Schedule II has a medical value, but of the legitimate
19 products that can be prescribed and dispensed it's the most
14:31:06 20 dangerous because of the toxicity, abuse, and addiction
21 potential. What you would find in this category would be
22 products like morphine or oxycodone.

23 Schedule III, going down the schedule, is not as
24 dangerous as Schedule II, but clearly more dangerous than
14:31:24 25 Schedules IV and V. And within Schedule III you would have

Catizone - Direct (By Mr. Feran)

1 combination products like hydrocodone and Tylenol or
2 hydrocodone and aspirin.

3 Schedule IV, again going down, is less dangerous than
4 III, but more dangerous than V, and those are products that
14:31:41 5 would treat anxiety, such as Valium or Xanax.

6 And then Schedule V are still controlled because
7 there's a potential, but the potential is not as great as
8 the upper schedules. And you may have products that you can
9 buy over the counter from the pharmacist if you sign a log,
14:31:58 10 and those may be products to treat a cough or to treat
11 diarrhea.

12 **Q.** So hydrocodone is classified as a Schedule III drug,
13 sir?

14 **A.** Yes, sir.

14:32:06 15 **Q.** Now, those are the controlled substances. Are you
16 familiar with noncontrolled substances?

17 **A.** Yes, sir.

18 **Q.** Can you explain what a noncontrolled substance is?

19 **A.** Within that prescription drug category, a
14:32:17 20 noncontrolled substance may be something that's used to
21 treat diabetes or high blood pressure, or an infection,
22 something that doesn't have any potential for abuse or
23 addiction.

24 So you may have like amoxicillin, you may have
14:32:31 25 products Torsemide that helps relieve water and helps reduce

Catizone - Direct (By Mr. Feran)

1 blood pressure, those types of medications.

2 **Q.** Mr. Catizone, are you familiar with the types of
3 products or substances that a pharmacy typically
4 distributes?

14:32:45 5 **A.** Yes.

6 **Q.** Can you tell us what those are, sir, and define them
7 for us, please?

8 **A.** Sure. Based upon my experience as a pharmacist and
9 the information I've seen over the years, a typical pharmacy
14:32:56 10 will dispense products for diseases such as asthma,
11 diabetes, high blood pressure, and then perhaps pain
12 medications or other controlled substances.

13 The usual mix of prescription drugs that are
14 controlled and noncontrolled that is documented in the
14:33:14 15 literature averages about 92 to about -- 92 to about 98
16 percent that are noncontrolled substances to the controlled
17 substances a typical pharmacy would dispense may be anywhere
18 in the range from 8 to 10 percent total.

19 So a pharmacy would go 92 to 90 percent of regular
14:33:36 20 noncontrolled, and 8 to 10 percent of controlled substances.

21 **Q.** So Mr. Catizone, let's focus on the 8 to 10 percent of
22 the controlled substances if we could. Are these all in a
23 particular drug class or are they in different drug classes?
24 Can you explain that to us, sure?

14:33:53 25 **A.** Sure. It would be a mix of drugs. You would have

Catizone - Direct (By Mr. Feran)

1 patients that would come in for pain medications, patients
2 that might come in for antianxiety drugs, or medications
3 they may need to help them sleep. So within that 8 to 10
4 percentage it would also be a mix of products.

14:34:10

5 **Q.** What would be some of the common names, sir, in the 8
6 to 10 percent of controlled substances that we would
7 recognize and a pharmacy would distribute?

14:34:27

8 **A.** Some of the brand names might be products like Vicodin
9 or Lortab, you may have Valium or Xanax, you may have
10 Ambien, products to help patients sleep.

11 **Q.** Mr. Catizone, have you given presentations on the
12 topic of Internet pharmacies?

13 **A.** Yes, sir.

14 **Q.** Can you tell us about that, sir?

14:34:40

15 **A.** I've been able to present before both the U.S. House
16 and U.S. Congress, and have presentations before the Board
17 of Pharmacy or the state legislature in every state except
18 for Alaska.

14:34:57

19 **Q.** So you've been to every state except for Alaska to
20 present at the Boards of Pharmacy?

21 **A.** Yes, sir.

22 **Q.** So Alaska is still on your bucket list, sir?

23 **A.** It's on my list.

14:35:05

24 **Q.** What has your presentation been before the House and
25 Senate for the state pharmacy boards? For what purpose did

Catizone - Direct (By Mr. Feran)

1 you appear in front of them, sir?

2 **A.** We were asked to present to educate them about
3 Internet pharmacies, some of the things we were observing,
4 and suggestions we had for regulating Internet pharmacies.

14:35:19 5 **Q.** What were some of the suggestions you had to regulate
6 Internet pharmacies?

7 **A.** Our suggestions were that the laws of the state needed
8 to be enforced, and so we needed more resources for the
9 states; that Internet pharmacies are regarded the same as
14:35:32 10 traditional brick and mortar pharmacies, and that there's an
11 important interplay between federal and state laws to make
12 sure Internet pharmacies are properly regulated.

13 **Q.** We'll get back to the law part in a moment, sir. Have
14 you spoken on national TV or radio on the topic of Internet
14:35:53 15 pharmacies?

16 **A.** Yes, sir.

17 **Q.** Can you tell us about that, sir?

18 **A.** I've been able to appear on such programs as Oprah,
19 The Today Show, Good Morning America, all the major evening
14:36:03 20 news programs, as well as local and national news programs.
21 CNN, and other local programs.

22 **Q.** And when you appeared on these various shows,
23 Mr. Catizone, what did you talk about?

24 **A.** The dangers of Internet pharmacies that are operating
14:36:19 25 illegally or rogue pharmacies, and then advice for consumers

Catizone - Direct (By Mr. Feran)

1 on how to identify legitimate pharmacies and how to use the
2 Internet safely.

3 **Q.** And what time period, Mr. Catizone, were you appearing
4 on Oprah and CNN and Good Morning America? What time period
14:36:35 5 are we talking about, sir?

6 **A.** Probably 1999 to the present.

7 **Q.** And the same question regarding your testimony before
8 the House and the Senate and various state pharmacy boards.

9 **A.** Yes, sir.

14:36:43 10 **Q.** What time period are we talking about there, sir?

11 **A.** The same time period, sir.

12 **Q.** Sir, have you ever published articles in the area of
13 Internet pharmacies?

14 **A.** Yes.

14:36:53 15 **Q.** Can you tell us about that?

16 **A.** I have about a hundred publications and presentations.
17 Most of them are on Internet pharmacy. They've appeared in
18 refereed journals. They've also appeared in the *Wall Street*
19 *Journal* and other national and local publications, *Reader's*
14:37:09 20 *Digest*, *Consumer Reports*, various consumer educational
21 magazines, newspapers, and other periodicals.

22 **Q.** You say professional journals, sir?

23 **A.** Yes.

24 **Q.** Can you explain what a professional journal is?

14:37:22 25 **A.** A professional journal is something that has to be

Catizone - Direct (By Mr. Feran)

1 reviewed by an independent panel to make sure that
2 information is credible and it's not promotional in any way,
3 and I've been able to publish in some of those journals, as
4 well.

14:37:32 5 **Q.** And, sir, were you the author of these articles?

6 **A.** Yes.

7 **Q.** Sir, have you ever testified as an expert in federal
8 court?

9 **A.** Yes, sir.

14:37:39 10 **Q.** And can you tell us how many times?

11 **A.** Approximately 12 times.

12 **Q.** Can you tell us, sir, some of the various federal
13 courts you've testified in?

14 **A.** I've testified in Minnesota, California, Illinois, a
14:37:53 15 number of different states.

16 **Q.** Mr. Catizone, are you being compensated for your
17 testimony today?

18 **A.** No, sir.

19 MR. FERAN: Your Honor, at this time I would
14:38:04 20 ask that Mr. Catizone be qualified as an expert in the area
21 of Internet pharmacy.

22 THE COURT: He may, he may testify.

23 MR. FERAN: Pardon me, Your Honor?

24 THE COURT: I said I will admit him to
14:38:15 25 testify.

Catizone - Direct (By Mr. Feran)

1 MR. FERAN: Thank you, Your Honor. As an
2 expert in Internet pharmacy and pharmacy practice, Your
3 Honor. Thank you, Judge.

4 THE COURT: All right.

14:38:26 5 Q. Let's talk about, Mr. Catizone, you talked earlier
6 about graduating from the University of Illinois with your
7 bachelor's and your pharmacy degree. Is that correct, sir?

8 A. Yes, sir.

9 Q. And after that, after you graduated did you take a
14:38:38 10 test to become a pharmacist?

11 A. Yes, sir.

12 Q. Can you tell us very briefly about that, sir?

13 A. Every pharmacist is required to take a national
14 licensure exam that tests their competence to practice, and
14:38:48 15 it focuses on areas of practice that affect patients'
16 health, clinical areas, as well as a state law exam, so I
17 took the Illinois state law exam.

18 Q. And for example, when you took the Illinois law exam,
19 sir, was there state law on your test?

14:39:01 20 A. It was both state and federal law that a pharmacist is
21 responsible for and needs to know.

22 Q. And what state law was on your exam, sir?

23 A. Illinois.

24 Q. Sir, have you developed a knowledge as to state
14:39:13 25 requirements for each state of the United States?

Catizone - Direct (By Mr. Feran)

1 **A.** Yes. We also serve as a resource for the states and
2 for Congress and the Senate, so we have all of the state
3 practice acts and regulations in a computer database that we
4 use all the time to provide information to research
14:39:30 5 questions or to provide information for task forces or
6 committees we may have.

7 **Q.** Mr. Catizone, can you tell us briefly, prior to your
8 testimony today did you review various documents in advance
9 of your testimony?

14:39:48 10 **A.** Yes, sir.

11 **Q.** Can you summarize, sir, what some of those documents
12 were.

13 **A.** I reviewed a number of documents pertaining to
14 undercover purchases that the government made, those
14:39:58 15 documents were actually written reports, transcripts of the
16 phone conversations, the actual tapes of the phone
17 conversations. I review various reports summarizing
18 prescription data and summarizing the distribution of
19 products prepared by the government, as well as actual
14:40:17 20 prescriptions dispensed by the pharmacies that were involved
21 in this case.

22 **Q.** Mr. Catizone, let's segue here and talk about an
23 individual wants to open up a pharmacy. Can you tell us
24 generally speaking what they have to do to do this?

14:40:32 25 **A.** They have to file an application with the state, and

Catizone - Direct (By Mr. Feran)

1 there are a number of requirements that that individual or
2 that pharmacist has to comply with involving having a
3 licensed pharmacist responsible for that pharmacy, as well
4 as meeting all the requirements for security, securing the
14:40:50 5 drugs, and then dispensing the drugs, in accordance with all
6 the state and federal laws and regulations.

7 **Q.** So state and federal law comes into play here?

8 **A.** Yes, sir.

9 **Q.** Now, you mentioned the word pharmacy. Is there a
14:41:04 10 difference between a brick and mortar and an Internet
11 pharmacy?

12 **A.** No, sir, the same requirements in terms of their
13 compliance with state and federal laws.

14 **Q.** You talked about registration requirements, sir?

14:41:16 15 **A.** Yes.

16 **Q.** Are pharmacies required to register with the DEA?

17 **A.** If they're going to be dispensing controlled
18 substances, which I mentioned earlier, they would register
19 with the DEA, and they register with the state, as well.

14:41:30 20 **Q.** Can you explain, Mr. Catizone, why registration with
21 the DEA is required for distributing controlled substances?

22 **A.** The regulation of controlled substances comes under
23 federal and state jurisdiction. The federal jurisdiction is
24 the Controlled Substance Act, and under that act it calls
14:41:47 25 for the DEA to register pharmacies, doctors, and other

Catizone - Direct (By Mr. Feran)

1 registrants so that the DEA has direct involvement and
2 oversight of activities involving controlled substances.

3 **Q.** If a pharmacy, Mr. Catizone, has to desire to
4 distribute controlled substances, is DEA registration
14:42:05 5 required?

6 **A.** It's not required.

7 **Q.** Now, you talked about DEA registration. You talked
8 about applications, sir. Can you tell us about that?

9 **A.** An application they would file with the state, it
14:42:17 10 could be a paper or electronic application. It sets out the
11 requirements that that pharmacy needs to comply with and
12 demonstrate to the state that it's met prior to that
13 pharmacy actually being issued a registration or permit and
14 actually being able to practice.

14:42:30 15 **Q.** So these are the general requirements by
16 state -- these requirements, excuse me, vary by state, sir?

17 **A.** Yes, they do, but not significantly. They're pretty
18 similar from state to state.

19 **Q.** Did your organization, NABP, launch an Internet
14:42:46 20 pharmacy program to distinguish between legitimate and
21 illegitimate pharmacies?

22 **A.** Yes, we did.

23 **Q.** Can you tell us about that, sir?

24 **A.** Sure. In 1999 we launched the Verified Internet
14:42:59 25 Pharmacy Prescription Site program, VIPPS. V-I-P-P-S. What

Catizone - Direct (By Mr. Feran)

1 it does is requires Internet pharmacies to submit
2 documentation to us. It shows us their compliance with
3 state and federal laws and standards of practice, as well as
4 all the policies and procedures that that pharmacy has in
14:43:16 5 effect.

6 So for example, one of the criteria talks about making
7 sure that they have licensed pharmacists responsible for the
8 pharmacy. That pharmacy has to have a procedure in place to
9 verify the license of that pharmacist before they can hire
14:43:32 10 that pharmacist and allow them to run the pharmacy.

11 We then physically inspect every aspect of that
12 pharmacy. If it has a call center, if it has a distribution
13 center, or if it's even just one pharmacy that has all those
14 operations within its one site, we physically send
14:43:51 15 inspectors out there to verify that what they're doing is
16 exactly what they've told us in their application.

17 **Q.** You talked, sir, about the legitimacy of a
18 prescription. Can you explain that?

19 **A.** Sure. One of the responsibilities that a pharmacist
14:44:03 20 has is that they have to make sure that the prescription is
21 valid before they can dispense it. And there are generally
22 three areas that the pharmacist has to look at before they
23 can dispense that prescription. One, is it a valid
24 prescription. And the way the pharmacist determines if it's
14:44:20 25 a valid prescription is whether or not that patient has a

Catizone - Direct (By Mr. Feran)

1 valid relationship with a physician or a doctor.

2 And the way that's established further is that that
3 patient has to have a medical condition. The physician or
4 doctor has to have conducted a medication history and a
14:44:41 5 face-to-face physical examination, and then there has to be
6 some logical connection between the medical condition, the
7 medication history, and the examination that the physician
8 has provided. That's one area.

9 The second area is to make sure that the medication is
14:44:59 10 appropriate for the patient. You wouldn't want the
11 physician to prescribe medications for a child that were at
12 adult doses because those medications would hurt the child,
13 or medications that the patients may be allergic to. So the
14 pharmacist has a responsibility to make sure that those
14:45:18 15 prescriptions are appropriate for that patient.

16 And then finally, the pharmacist has a responsibility
17 to make sure there's no fraud or diversion occurring. If
18 the patient maybe stole prescription blanks, forged the
19 doctor's signature, or if there was not a valid relationship
14:45:35 20 and a pharmacist suspected there was some fraud or
21 diversion, the pharmacist has to act in that situation to
22 call the doctor or not fill the prescription, but make some
23 sort of professional judgment. And if there's a suspicion
24 of fraud or diversion there's also a responsibility to
14:45:51 25 report that to the DEA and to the Board of Pharmacy or other

Catizone - Direct (By Mr. Feran)

1 local authorities.

2 **Q.** Now, Mr. Catizone, during what time frame in the
3 distribution process does this analysis take place? The
4 relationship, the validity of the medication to the patient,
14:46:12 5 and no fraud, what part of the prescription distribution
6 process does that take place?

7 **A.** All of that has to occur before the pharmacist
8 dispenses the medication to the patient.

9 **Q.** And was this in place, sir -- what years was this in
14:46:24 10 place?

11 **A.** This has been in place for traditional brick and
12 mortar pharmacies and Internet pharmacies as far back as
13 practice exists, and some of the research I conducted from
14 2001 moving forward, it was specifically addressed for
14:46:44 15 Internet pharmacies in at least 15 states. And that
16 requirement is still in place and has been expanded to just
17 about all of the states, if not all of the states.

18 **Q.** Originally in 15 states, sir?

19 **A.** Yes.

14:46:57 20 **Q.** When you say originally, what time frame are we
21 talking about here?

22 **A.** In 2001 and 2005 were specific Internet references
23 even though those standards existed prior to that, because
24 an Internet pharmacy would be considered a pharmacy in all
14:47:12 25 practical purposes, and you have to follow the same

Catizone - Direct (By Mr. Feran)

1 requirements.

2 **Q.** Mr. Catizone, you talked about 15 states. What are
3 some of the states that this three-bullet criteria was in
4 place for?

14:47:22 5 **A.** North Carolina, Florida, Texas, Indiana, to name just
6 a few.

7 **Q.** You talk about the valid relationship, sir. And can
8 you further explain to us what you mean by a valid
9 relationship in the context of a prescription in a
14:47:44 10 pharmacist dispensing situation?

11 **A.** I just mentioned what the pharmacist has to do to
12 validate that there's a valid prescription patient
13 relationship. That responsibility falls on the pharmacist
14 as well to ascertain that. So if there's a question, if
14:47:57 15 they think that there isn't a relationship, the patient has
16 to call the doctor and verify that. If it doesn't exist
17 then the pharmacist cannot fill that prescription.

18 **Q.** What steps, Mr. Catizone, have you taken if you are
19 concerned about the validity of a relationship?

14:48:15 20 **A.** The steps that are required under the VIPPS program
21 and within all the practice acts and regulations is to
22 validate that prescription directly with the doctor, as well
23 as to insure that that patient is a legitimate patient, and
24 to verify the identity and validity of that patient, as
14:48:34 25 well.

Catizone - Direct (By Mr. Feran)

1 **Q.** Now, these rules, sir, are placed on brick and mortar
2 and Internet pharmacies?

3 **A.** Yes, sir.

4 **Q.** Are you familiar with the term, Mr. Catizone,
14:48:43 5 corresponding responsibility?

6 **A.** Yes, sir.

7 **Q.** Can you tell us what that is?

8 **A.** That's the responsibility where I just mentioned that
9 the pharmacist has the same responsibilities as the doctor
14:48:52 10 in determining that the prescription is valid and the
11 patient is valid, and that the medication is appropriate for
12 that patient.

13 **Q.** We're talking about VIPPS. How does that VIPPS
14 pharmacist insure that a patient-physician relationship
14:49:03 15 exists with every prescription? Can you explain that, sir?

16 **A.** Sure. For a VIPPS Internet pharmacy the prescriptions
17 have to be sent to the pharmacy directly from the doctor's
18 office or phoned in by the doctor. Patients are not allowed
19 to send their prescriptions to the Internet pharmacy.
14:49:19 20 They're not allowed to complete and select medications off
21 of a form or questionnaire. That would violate the
22 criteria, as well as state and federal laws. And if there's
23 any question about the validity of that doctor-patient
24 relationship the VIPPS pharmacy has to call and document
14:49:37 25 that verification.

Catizone - Direct (By Mr. Feran)

1 **Q.** Why is this, sir?

2 **A.** One, prescription drugs are generally dangerous, and
3 that's why they're controlled. It requires a doctor's
4 prescription and a pharmacist to dispense it. And
14:49:49 5 controlled substances are even more dangerous than that, and
6 therefore there's the additional stringent requirements to
7 help people from being harmed by these products.

8 **Q.** Now, we're talking about VIPPS. How many VIPPS are
9 there, sir, in the United States?

14:50:01 10 **A.** There are 32 VIPPS pharmacies, and they range from
11 multistate pharmacies like CVS.com or Walgreens.com that
12 have 5,000 and 6,000 pharmacies, to individual pharmacies
13 that simply have one site, one pharmacist.

14 **Q.** Now, let's stay with CVS for example. Is that a VIPPS
14:50:20 15 pharmacy, sir?

16 **A.** Yes, sir.

17 **Q.** Now, there are how many CVSs throughout the United
18 States?

19 **A.** Approximately 6,000.

14:50:25 20 **Q.** Now, do they count as one in the VIPPS category of
21 pharmacies?

22 **A.** Yes, sir.

23 **Q.** So when you say 32, a large chain would count as one
24 VIPPS pharmacy for purposes of discussion?

14:50:34 25 **A.** Correct.

Catizone - Direct (By Mr. Feran)

1 **Q.** And is there a financial requirement or a financial
2 component to VIPPS?

3 **A.** Yes. We charge a fee for the pharmacies based upon
4 the size of their operation, so one pharmacy would pay us a
14:50:50 5 fee of about \$3,000 for a three-year period, the larger
6 pharmacies may pay anywhere between 8 to \$10,000, and that's
7 for multistate operations. And it's actually a revenue loss
8 for us, for each accreditation we lose money on that
9 process, so it's something that we subsidize and provide for
14:51:12 10 the state boards and patients so there's a way of
11 identifying safe and legitimate pharmacies.

12 **Q.** And becoming a member of VIPPS, Mr. Catizone, what
13 does your organization offer to the pharmacies?

14 **A.** It's the accreditations process. They have to meet
14:51:30 15 the standards and laws and demonstrate that, and what they
16 receive is simply recognition that they've met those
17 standards, and they are a legitimate and safe pharmacy.

18 **Q.** Mr. Catizone, do you have to be a member of VIPPS to
19 distribute controlled substances over the Internet?

14:51:44 20 **A.** No. There are a number of pharmacies that perhaps may
21 advertise on the Internet or may use the Internet for their
22 patients. If they're not using, getting prescriptions from
23 other states or other patients, there's no requirement. The
24 only requirement is that both Google and Microsoft will not
14:52:03 25 allow a pharmacy to advertise on Google or Microsoft unless

Catizone - Direct (By Mr. Feran)

1 they're accredited by us because of the problems they
2 encountered with rogue pharmacies and because of the value
3 they've seen in our accreditation program.

4 **Q.** Sir, you mentioned earlier that 97 percent of online
14:52:23 5 pharmacies were illegal. Is that correct?

6 **A.** Yes, sir.

7 **Q.** Are you familiar with a rogue pharmacy?

8 **A.** Yes, sir.

9 **Q.** What do you know that to be, sir?

14:52:29 10 **A.** That's a term that's been coined and applied to those
11 Internet pharmacies that are operating illegally or not
12 operating legitimately.

13 **Q.** And for example, sir, how did this occur?

14 **A.** The primary reason that we have found for these
14:52:45 15 pharmacies to be classified as rogue or illegal is that
16 they're offering medications without a valid prescription or
17 they're located outside of the United States, or they're
18 dispensing drugs that have not been approved by the Food and
19 Drug Administration.

14:53:00 20 **Q.** You mentioned, Mr. Catizone, valid prescription. Can
21 you define a valid prescription for us?

22 **A.** I did, it was the components we talked about earlier
23 about the patient has a medical condition, that there's a
24 medication history, a physical examination face to face, and
14:53:18 25 a connection between the medical condition and the

Catizone - Direct (By Mr. Feran)

1 prescription.

2 **Q.** What are some of the things, Mr. Catizone, that would
3 make a prescription suspicious?

4 **A.** Based upon, again, the research that we've done, some
14:53:32 5 of the things that would be red flags for pharmacists would
6 be whether or not that prescription and patient and
7 pharmacist were located in the same area. So that if a
8 pharmacist saw a prescription for a doctor for patients that
9 were located in different states and there did not appear to
14:53:52 10 be a relationship between that doctor and patient, that
11 would be a red flag.

12 Prescriptions that are written for different patients
13 for the same drug, the same quantity, the same strength,
14 would be a red flag because no two people are alike, and the
14:54:10 15 dosages would vary with individuals with almost any
16 medication.

17 Sending prescriptions for multiple patients to the
18 same address, again, without verifying why that existed, as
19 well as having medications written by a doctor for multiple
14:54:29 20 patients with so many on one day or multiple days that there
21 doesn't appear to be an opportunity for that doctor to
22 establish a relationship with that patient.

23 Those are some of the signs.

24 **Q.** These are the signs of prescriptions, sir, which are
14:54:48 25 suspicious?

Catizone - Direct (By Mr. Feran)

1 **A.** Yes, sir.

2 **Q.** Sir, who has to do the medical history and the
3 examination and prescribe the medication? Who does that?

4 **A.** That would be conducted by the physician or the
14:55:03 5 physician assistant, or the physician's agent that's
6 directly supervised by that physician.

7 **Q.** We talked earlier, sir, about the types of drugs the
8 pharmacies distribute. Let's talk about the different types
9 of pharmacies. Can you define for us what the term mail
14:55:25 10 order means?

11 **A.** Sure. Mail order is a pharmacy that's located in one
12 state but then may ship prescriptions to another state.
13 What separates a mail order pharmacy from an Internet
14 pharmacy, again, based upon our accreditation program and
14:55:42 15 our experiences, is that the mail order pharmacies have a
16 defined patient population. You have to be a member of a
17 health care plan that that pharmacy will serve, or perhaps
18 where you work had signed on with that pharmacy, so people
19 have to go to that mail order to get their prescriptions
14:56:00 20 filled. So the mail order knows their patients and only
21 patients that are members of those plans or that have been
22 approved by that mail order can actually use that service.

23 **Q.** Can you give us an example, Mr. Catizone, of a mail
24 order situation?

14:56:14 25 **A.** Sure. Express Scripts or Medco are two of the largest

Catizone - Direct (By Mr. Feran)

1 mail orders. You cannot simply go to their websites and try
2 and register and become a patient of those sites. Your
3 health care plan or your employer must qualify you, and then
4 you will have access because they'll issue you an ID number
14:56:35 5 and other qualifying information for you to be able to use
6 those pharmacies.

7 **Q.** Based on your training and experience, what type of
8 drugs do mail order pharmacies typically distribute?

9 **A.** They'll primarily distribute noncontrolled substance
14:56:48 10 medications, because for a controlled substance if there's
11 an immediate need for that patient, if the patient is in
12 pain or suffering from some other condition that requires a
13 controlled substance, they'll generally refer them to a
14 local pharmacy that they have a relationship with or that's
14:57:03 15 close to the patient or convenient for the patient to
16 utilize.

17 **Q.** Let's talk about specialty pharmacies, if we could.
18 Strike that. I want to go back to mail order, sir. The
19 doctor-patient relationship, based on your experience, how
14:57:20 20 is it established?

21 **A.** The same requirement as brick and mortar. So the mail
22 order pharmacy has to document the doctors that are
23 prescribing and they have to establish that there's that
24 valid relationship. And if the mail order pharmacy has any
14:57:34 25 questions they have to call that doctor and verify that

Catizone - Direct (By Mr. Feran)

1 prescription, and document all those interactions.

2 **Q.** Let's talk, Mr. Catizone, about specialty pharmacies.

3 Are you familiar with that term, sir?

4 **A.** Yes.

14:57:47 5 **Q.** What is a specialty pharmacy?

6 **A.** A specialty pharmacy has been Ted dedicated because
7 they dispense special drugs, drugs that require special
8 preparation or drugs that require special administration or
9 require special monitoring of the patient.

14:58:06 10 So for example, a specialty pharmacy would distribute
11 hemophilia products, medication for patients whose blood
12 don't clot. Because those medications may cost \$16,000 a
13 month for one patient, they have to be prepared and they
14 have a very short expiration period for that period to
14:58:24 15 utilize that medication. And because with a hemophiliac the
16 condition changes and the medication has to be constantly
17 adjusted, that specialty pharmacy has to have expertise in
18 that area and be able to prepare and dispense those drugs to
19 make sure the patient gets the right medication. It's not
14:58:43 20 something they just walk into a typical pharmacy, give them
21 a prescription, and expect them to have that medication.

22 **Q.** What's hemophilia, for the record, sir?

23 **A.** It's a disorder where people's blood won't clot, and
24 it causes them to bleed.

14:58:57 25 **Q.** Sir, do pain medications, hydrocodone, fall into the

Catizone - Direct (By Mr. Feran)

1 specialty pharmacy category?

2 **A.** No, sir.

3 **Q.** Can you explain that, sir?

4 **A.** Pain medications are one of the areas again that

14:59:11 5 pharmacists are trained in and are trained to dispense.

6 There are no pain medications that require special

7 preparation. The regulations, the training about how to

8 dispense and monitor controlled substances, are very clear.

9 They're supposed to be used for a short time period for

14:59:29 10 pain. If a person has chronic pain then they should be

11 involved in a special pain management program with a

12 certified pain management physician, and there has to be

13 very special monitoring of that patient.

14 **Q.** Sir, are you familiar with the term closed door,

14:59:47 15 closed shop?

16 **A.** Yes.

17 **Q.** Can you tell us what that is?

18 **A.** Closed pharmacy is simply a pharmacy that doesn't

19 accept walk-ins or people that would come into that pharmacy

14:59:57 20 to dispense prescriptions, and they may be providing

21 prescriptions or medicines to a nursing home or an assisted

22 living facility. They would prepare the medications, put

23 them in what people call blister packs or other reminders,

24 and then send those over to the pharmacy for the pharmacist

15:00:13 25 to dispense to other patients or residents that may be in

Catizone - Direct (By Mr. Feran)

1 that assisted living care facility.

2 **Q.** And an example of a closed-door pharmacy distribution
3 would be to?

4 **A.** Again, a nursing home, so it would be the whole gamut
15:00:27 5 of medications that patients in a nursing home would
6 require.

7 **Q.** Mr. Catizone, as a pharmacist, are you familiar with
8 the federal and state law and regulations and standards of
9 practice?

15:00:36 10 **A.** Yes, sir.

11 **Q.** Can you tell us about that, sir? Can you explain
12 those?

13 **A.** I mentioned earlier the two federal laws that govern
14 the manufacture of drugs, whether drugs are safe and
15:00:49 15 effective, and then the Controlled Substance Act, which
16 talks about the distribution and special requirements of
17 controlled substances. And then the state acts regulate
18 pharmacists and pharmacies as to what they must do for
19 patients.

15:01:00 20 **Q.** If we could stop there. So the federal laws that
21 we're talking about, Mr. Catizone, just so we're clear here,
22 are what, sir?

23 **A.** The Food, Drug, and Cosmetic Act and the Controlled
24 Substances Act.

15:01:11 25 **Q.** And those two acts are federal, and then you mentioned

Catizone - Direct (By Mr. Feran)

1 state laws, sir?

2 **A.** Every state has an individual state practice act, as
3 well as regulations in relation to the laws.

4 **Q.** And we have federal law, we have state law. Is there
15:01:29 5 an interplay between these laws, sir?

6 **A.** Yes. If we take the term valid prescription, what it
7 says at the federal law is that in order for a prescription
8 to be dispensed there must be a valid prescription. So
9 federal law sets the requirement that there must be a valid
15:01:46 10 prescription, but then it defers to state law, because the
11 states regulate the practices of pharmacy medicine in their
12 state to actually define what is a valid prescription. And
13 the states have defined what is a valid prescription, the
14 things I mentioned earlier, through laws and regulations, as
15:02:06 15 well as to standards of practice that have resulted from

16 court decisions or other documents or other processes that
17 have said this is a standard of care that applied to a valid
18 prescription, and helps define what a valid prescription is.

19 **Q.** And prior to testifying here today, Mr. Catizone, have
15:02:26 20 you reviewed Florida state law applicable to this case?

21 **A.** Yes, sir.

22 **Q.** And can you tell us, sir, about that?

23 **A.** I have reviewed some regulations that pertain to the
24 dispensing of controlled substances, pain management,
15:02:49 25 defining what controlled substances are, defining what a

Catizone - Direct (By Mr. Feran)

1 prescription is, and what a valid prescription is.

2 **Q.** And what time frame, sir, are we talking about here?

3 **A.** The Florida regulations again were enacted sometime
4 between 2001 and 2002.

15:03:22 5 **MR. FERAN:** Your Honor, permission to
6 approach?

7 **THE COURT:** You may.

8 **Q.** Sir, I'm handing you for identification purposes as
9 Government's Exhibit 999-D. Do you recognize that,

15:03:35 10 Mr. Catizone?

11 **A.** Yes, sir. It's one of the documents I reviewed.

12 **Q.** And can you explain, sir, what that document is?

13 **A.** The title of it is Standards of Practice for the
14 Dispensing of Controlled Substances for Treatment of Pain.

15:03:46 15 **Q.** And is that a standard or federal law, sir?

16 **A.** This is a standard -- this is a requirement of state
17 law.

18 **Q.** And what state are we talking about?

19 **A.** The state of Florida.

15:03:55 20 **Q.** And what law number is that, sir?

21 **A.** Board Regulation 64 B 16-27 dot 831.

22 **Q.** And are you familiar with that, sir?

23 **A.** Yes.

24 **Q.** Can you tell us, sir, how you are familiar with it?

15:04:09 25 **A.** I reviewed it for this case.

Catizone - Direct (By Mr. Feran)

1 **Q.** And Mr. Catizone, you have testified, you stated, in
2 49 of 50 states?

3 **A.** Yes.

4 **Q.** Have you testified before the Florida Board of
15:04:23 5 Pharmacy?

6 **A.** Yes, sir.

7 **Q.** Sir, what are the requirements in that law for the
8 dispensation -- for the distribution of a controlled
9 substance?

15:04:31 10 **A.** It sets out things that the pharmacist needs to
11 question about a prescription, and some of those things are
12 whether or not there's a frequent loss of controlled
13 substance medications. So if a patient keeps saying I lost
14 my prescription or my dog ate my prescription, that the
15:04:47 15 controlled substances medications are only prescribed for a
16 patient and the patient, so that somebody is not trying to
17 use some other identity or steal a patient's identity.

18 When one person presents controlled substances with
19 different patients' names and if the same or similar
15:05:06 20 controlled substance medication is prescribed by two or more
21 prescribers at the same time, you may have a patient that
22 may be seeing multiple doctors or you may have a patient
23 that receives the same medications from different doctors.

24 If the patient always pays with cash and always
15:05:23 25 insists on a brand name product. And if this occurs, the

Catizone - Direct (By Mr. Feran)

1 regulation is quite clear that what steps the pharmacist has
2 to take, and the pharmacist then has to ask for
3 identification. They're supposed to photocopy that, and
4 then they're supposed to verify the prescription with the
15:05:43 5 prescriber.

6 **Q.** Sir, I'm going to show you Government's Exhibit 999-A.
7 Sir, do you recognize that?

8 **A.** Yes, I do. It's a document that I've reviewed for
9 this case.

15:06:24 10 **Q.** Can you tell us about that, sir?

11 **A.** It's provided by the Federation of State Medical
12 Boards, which is a similar organization that to the
13 organization that I work for. And what it is, it's a
14 compilation of the disciplinary actions that states have
15:06:39 15 taken against physicians involved in Internet prescribing
16 and the reasons for the actions that those states took, and
17 it's a listing state by state.

18 I'm familiar with this because we work hand in hand
19 with the federation to prepare this document. We share
15:06:58 20 information on pharmacists with them and pharmacies, they
21 share information with us on physicians, and then we both
22 circulate that information to our respective members. So
23 this information goes to all the state medical boards, the
24 information we compile goes to all the state pharmacy
15:07:14 25 boards.

Catizone - Direct (By Mr. Feran)

1 Q. And on that document, Mr. Catizone, are there a number
2 of states listed?

3 A. Yes, sir.

4 Q. If you could page through that, is one of the states
15:07:22 5 the state of Florida?

6 A. Yes, sir.

7 Q. And is one of the states Ohio?

8 A. Yes, sir.

9 Q. What is the date of that document, sir?

15:07:42 10 A. Some of these actions date back to 1999 in Ohio and
11 continue to 2006. This was actually updated in 2008, but
12 the actions go as far back as that.

13 Q. As far back as 1999?

14 A. Yes, sir.

15:07:57 15 Q. Let's talk about Florida for a second. Can you focus
16 on that?

17 A. Sure.

18 Q. Can you tell us, Mr. Catizone, about Florida?

19 MR. DARKEN: Your Honor, can we get a copy of
15:08:06 20 the document?

21 Q. Mr. Catizone, can you tell us about Florida, sir?

22 A. Sure. There are numerous actions that the board has
23 taken action. For example, the board issued a statement in
24 December 1998 that a physician prescribing Viagra without
15:08:40 25 being licensed in Florida will be criminally liable. They

Catizone - Direct (By Mr. Feran)

1 imposed a \$10,000 fine on the physician prescribing through
2 the Internet without having face-to-face contact or
3 evaluation. They suspended the license --

4 MS. KIM: Your Honor, can we be heard, please?
15:08:56 5 May we approach?

6 THE COURT: Sure.

7 (Proceedings had at side-bar:)

8 MR. DARKEN: This is the document.

9 MS. RHA: This is Megan Rha with Dr. Sasaki.
15:09:24 10 Just a couple of things, Judge. First of all, I've never
11 seen this before, and second of all, Mr. Catizone seems to
12 be testifying on behalf of the Federation of State Medical
13 Boards --

14 THE COURT: Hold on a second.

15:09:38 15 (Proceedings had in open court:)

16 THE COURT: Feel free to stretch, and we're
17 going to take a break in a few minutes, but feel free to
18 stretch right now.

19 A JUROR: Thank you.

15:09:53 20 (Proceedings had at side-bar:)

21 THE COURT: Go ahead.

22 MS. RHA: Yes. He's here representing NABP,
23 and I understand that, but this line of questioning seems to
24 be it appears that he is testifying on behalf of FSMB, which
15:10:09 25 is the Federation of State Medical Boards. So on those two

Catizone - Direct (By Mr. Feran)

1 grounds I am objecting to his testimony along this line of
2 questioning, Judge.

3 MR. DARKEN: This is Kevin Darken for Darji.
4 I have two concerns in addition to what Ms. Rha said. One
15:10:27 5 is that this document is hearsay. It's just we don't know
6 who prepared it, we don't know where the data came from, so
7 I object on that grounds.

8 And secondly, this is the two-page expert report we
9 received from the government. That's all it is. And
15:10:53 10 there's nothing about this document in those two pages. So
11 I object under Rule 16, inadequate disclosure.

12 MR. GORENCE: For the record, Ms. Rovedo joins
13 those objections.

14 MS. LUTZKO: Your Honor, I would response on a
15:11:17 15 couple points. First of all, as to hearsay, Mr. Catizone
16 just testified that he and his organization worked with the
17 Federation of State Medical Boards in preparing this
18 document and providing it then to the local pharmacy boards
19 and their various members, and so he has personal
15:11:33 20 familiarity with this document, number one.

21 Number two, the defendants have in this case, as you
22 know, brought up the Federation of State Medical Boards and
23 tried to get in pieces/parts of what that Federation of
24 State Medical Boards has put out regarding the Internet.
15:11:51 25 They've unfairly characterized what their position is in

Catizone - Direct (By Mr. Feran)

1 step after step after step, and so it's only fair to
2 complete the picture here.

3 They also -- this witness, while he's not from this
4 Federation of State Medical Boards, they were
15:12:08 5 cross-examining people with the Federation of State Medical
6 Boards documents that these people had -- people who were
7 also not from that organization, and had not read, and were
8 again pulling out pieces/parts of those documents.

9 Further then, Your Honor, with respect to the law, the
15:12:27 10 government in its report and then further in the notice as
11 directed by the Court did state -- I'm sorry -- did state
12 the specific laws regarding Florida that upon which Dr.
13 Catizone is going to opine, as well as upon the fact that he
14 is going to rely on federal laws and other laws more
15:12:51 15 generally with respect to the other 50 states.

16 This is a case that is about distributions via the
17 Internet all over the country, and this general knowledge of
18 the defendant that the witness has is clearly relevant, and
19 it's not any -- they can cross him on it if need be.

15:13:13 20 MR. MILANO: Judge, may I be heard on this?
21 This document, Your Honor, we can't cross anybody on. This
22 document that they're having him go through is hearsay on
23 its face. He's not a keeper of the record, we don't know
24 where this document came from. It's some sort of an
15:13:24 25 Internet thing.

Catizone - Direct (By Mr. Feran)

1 When Miss Lutzko says we examined people on various
2 documents of various agencies, it was either on the laws of
3 Florida or a generally recognized position paper of this
4 organization which was signed by the organization, and the
15:13:38 5 witness, Dr. Nelson, adopted it as knowing about it. But
6 this particular document, Judge, is a synopsis of what may
7 have happened in front of a medical board. No one knows who
8 wrote this synopsis, no one knows what the facts are in this
9 synopsis. There's no indicia of reliability.

15:13:56 10 THE COURT: So the only way it would come in,
11 if it comes in this way, so I need to know whether this is
12 what the purpose is, we've been pretty broad across the
13 board in terms of what the relevant, so-called relevant
14 agencies, government agencies' positions were. I think that
15:14:25 15 the reason that people have been probing that is not to show
16 that necessarily the activity is wrong, but whether they had
17 knowledge that it was wrong or not wrong, so whether it is
18 or not.

19 The issue is, is this something that people would have
15:14:50 20 been knowing about, would likely to have been informed
21 about, would have likely been on their radar screen
22 generally. That's the way I think you are approaching the
23 issue. So it is not -- I mean, he can't just read the
24 report if all it was was somewhere in the United States or
15:15:11 25 somewhere in Florida somebody was disciplined for not having

Catizone - Direct (By Mr. Feran)

1 face-to-face. That would just be equating to legal
2 decisions. But if the notion is that the people who are
3 regulated somehow would normally have been expected to see
4 these things, they could take that into consideration. They
15:15:31 5 could obviously decide, no, that's not me, I'm not going to
6 abide by that, or I think they're wrong, but it would relate
7 to whether or not they'd have knowledge.

8 To me, that's my question, frankly, of hearsay, it's a
9 question of whether the interpretation of the law is right
15:15:52 10 or wrong, then would they have been on notice that the board
11 was taking a position -- the board was taking a position
12 that this wasn't correct. And so that's how I see it.

13 MR. MILANO: But however, Judge, this is much
14 more, much more truncated than that. It's not as if they're
15:16:17 15 introducing the medical board opinion which says this and
16 people could have known about and seen the facts and could
17 have accepted or rejected them. The reason this is
18 unacceptable hearsay, this is just a synopsis made by an
19 unidentified third party of what the medical board said. No
15:16:34 20 one could have seen this synopsis --

21 THE COURT: Now, what we need to know is we
22 need to hear the foundation on his knowledge. I think he's
23 testified to some of it, how it was prepared. It doesn't
24 matter, it's not the accuracy, it's the question is, is this
15:16:57 25 the kind of document that would get disseminated. It could

Catizone - Direct (By Mr. Feran)

1 be wrong, it could be these blurbs. And why I say it's not
2 the hearsay, it's not that they were right, but I think, you
3 know, you can get a curative instruction if you want, but
4 that's the way I see it.

15:17:20 5 MR. MILANO: My suggestion is that
6 this -- first of all, he's not a member of this
7 organization.

8 THE COURT: He doesn't have to be if he's a
9 person who can testify that that's the kind of document that
15:17:32 10 he's familiar with. There's no reason, because a person can
11 testify to that who has some position in the profession who
12 is prepared to testify about what people normally receive in
13 the profession. As lawyers you could testify about what
14 people as early as X date, there were these opinions being
15:17:54 15 disseminated in bar journals, or whatever, so a person who
16 kept up with what was going on would know that. That's all
17 I'm saying.

18 MR. MILANO: Understood, Judge. And if they
19 had the actual medical board action, that would be
15:18:08 20 different. But what if --

21 THE COURT: It doesn't matter.

22 MR. MILANO: But in terms of the synopsis,
23 this says without having a face-to-face relationship. What
24 if there's another fact in there and he didn't have a
15:18:20 25 face-to-face relationship, and they didn't review medical

Catizone - Direct (By Mr. Feran)

1 records.

2 THE COURT: The only question is, this is
3 limited, this is information for a limited purpose because
4 it's obvious you can cross-examine on something like this.
15:18:31 5 The question is whether factually all that is right because
6 that's not where we're going. The question is, can he show
7 that this is something which would have been -- you know,
8 you could point out, well, nobody would rely on that because
9 there's not enough facts there, but that's the way I see it.

15:18:50 10 Lay the foundation, and if you lay a proper
11 foundation -- if not, then we have to move on. Let's take a
12 break.

13 MR. DARKEN: Your Honor, for the record, I
14 object, number one. Number two, the government represented
15:19:03 15 to the Court earlier it was going to introduce the full
16 federal -- I mean Federation of State Medical Boards
17 document. Is that coming in?

18 MS. LUTZKO: I'm not sure. I'm not sure
19 what -- I didn't make any representations in Court.

15:19:15 20 MR. DARKEN: Mr. Feran did.

21 MS. LUTZKO: To the Court? We may have
22 discussed it with you, but we did not represent to the
23 Court.

24 MR. DARKEN: No, when we were up here. Mr.
15:19:23 25 Feran said he was going to admit --

Catizone - Direct (By Mr. Feran)

1 MR. FERAN: Are you talking about the one
2 you've been talking about the last two days with Dr. Nelson?

3 MR. DARKEN: Yes.

4 MR. FERAN: I'm going to have the witness read
15:19:31 5 the entire section that having been parsed out --

6 MR. DARKEN: That's fine.

7 THE COURT: Okay.

8 MR. DARKEN: Are we taking a break?

9 THE COURT: Now.

15:19:56 10 (Proceedings had in open court:)

11 THE COURT: I could have given you a longer
12 break if I had anticipated it, so you get 15 minutes now.
13 You could have had maybe 25 if I had thought about it,
14 right? Okay?

15:20:10 15 A JUROR: Okay. 15.

16 THE CLERK: All rise.

17 (Recess had.)

18 (Proceedings in the presence of the Jury:)

19 THE COURT: Okay. Just before I see counsel
15:42:42 20 again, because I understand there's a request, let me just
21 give everybody the schedule.

22 The lawyers know the schedule already, I think they
23 may have forgotten based upon one thing Mr. Feran said the
24 other day, I think. So this week and next week we're
15:43:03 25 following the same format. Those are both short weeks, and

Catizone - Direct (By Mr. Feran)

1 then after that we're back on a full schedule.

2 So tomorrow, I already told you this much, we are
3 meeting for one half day. We're going to 12:30. All right?
4 So you should be here ready at 8:30.

15:43:30 5 Is that a problem?

6 ALL: No.

7 THE COURT: I thought I saw a face there that
8 showed a problem. Okay. So Friday we're not going to hold
9 court. You knew that.

15:43:41 10 Okay. Just as we missed this Monday, we'll miss next
11 Monday. We'll start on Tuesday. We'll go Wednesday, and
12 we'll go a half a day on Thursday. And then after that the
13 following week will be a full five days.

14 Now, let me tell you that I do give this case a
15:44:02 15 priority. When we get to a point in trying a case, that's
16 what I do. I've cleared off everything that I possibly
17 could. You know that I have a lot of other cases, but I
18 also in my position as Judge on the Court, as Chief Judge I
19 have a number of responsibilities both in and out of the
15:44:21 20 district, and there are just some things that I had to do
21 that were previously scheduled and important enough that I
22 had to try to accommodate them. But I thought also this
23 gives in a long trial everybody some chance to catch their
24 breath, and if there are things you need to do you can get
15:44:44 25 them done.

Catizone - Direct (By Mr. Feran)

1 So that's the schedule, and after next week, which
2 will be exactly the same as this week, we'll have the full
3 five days schedule. All right? It's the same as this week.
4 So you will have Tuesday, Wednesday, half a day Thursday,
15:45:08 5 not Friday. Okay. That's what I mean.

6 Okay. Counsel, I don't know -- Mr. Darken?

7 (Proceedings at side-bar:)

8 THE COURT: You asked to come again.

9 MR. DARKEN: Your Honor, maybe you can take my
15:45:34 10 highlighted copy and I could take your clean copy.

11 May I begin, Your Honor?

12 THE COURT: If you want me to read this, let
13 me look.

14 MR. DARKEN: I've only highlighted the Florida
15:46:00 15 section, and I started to highlight the other sections, but
16 that middle column is rife with criminal indictments,
17 criminal guilty pleas, other types of announcements of
18 indictments, and I asked Mr. Feran and Ms. Lutzko are they
19 planning to introduce this document, and they indicated they
15:46:25 20 were. And so that's what they're planning to get the jury
21 to see. And I cannot have a fair trial for my client, as is
22 his constitutional right, if that document goes to the jury.
23 There is just no way. And the case is going to be reversed
24 if there's a conviction, and we're going to be back here
15:46:46 25 retrying this case.

Catizone - Direct (By Mr. Feran)

1 THE COURT: Are you going to promise reversal
2 on me before I even make a ruling?

3 MR. DARKEN: I'm feeling good.

4 THE COURT: Of course, I'm intimidated by
15:46:56 5 that.

6 MR. DARKEN: I'm feeling good, Your Honor.

7 That is just so prejudicial, it is just showing all
8 these people were indicted, pled guilty, convicted at trial.

9 THE COURT: Okay.

15:47:15 10 MR. DARKEN: That whole column should be
11 redacted. If any of this is going to go to the jury none of
12 the criminal stuff should go back to the jury, for sure.
13 And there's no need, there's no purpose. It is just totally
14 prejudicial.

15:47:29 15 THE COURT: Okay. Well, just let me -- does
16 the government feel a need to put in all the criminal
17 indictments, and so forth, as opposed to these other medical
18 board actions?

19 MS. LUTZKO: Your Honor, I would say that the
15:47:59 20 argument is the same as far as whether or not this was
21 disseminated to the public and to the state boards.
22 However, I think we would be agreeable, even though it's
23 certainly relevant conduct -- I'm sorry -- it's relevant
24 information that was made available to the public about the
15:48:17 25 problems in these types of distributions, we would be

Catizone - Direct (By Mr. Feran)

1 agreeable to removing that column.

2 THE COURT: I don't think it's irrelevant. I
3 would agree with you, I think it is more a 403 issue. I
4 think some of it might be relevant, depending. You have to
15:48:38 5 go through them and see whether whatever is in the
6 conviction or the indictment would be detailed enough that
7 one could get any notice as about their own conduct. That
8 would be a concern, as well, I mean, to just put them all
9 in. So if you would redact that, that would solve our
15:49:03 10 problem, potential problem, because as Mr. Darji says, he
11 would go straight to the circuit.

12 MS. LUTZKO: Well, we would disagree with him
13 on that point. We would nonetheless agree to redact it.

14 THE COURT: Right. If you have a legal
15:49:18 15 position that would make sense stick with it, but there's no
16 reason to unnecessarily have problems.

17 MS. LUTZKO: And we will agree to do that.

18 THE COURT: All right.

19 MR. MILANO: Judge, just so the record is
15:49:32 20 clear, on behalf of Mr. Sasaki, we object to the whole
21 document.

22 MR. DARKEN: So do I, Your Honor.

23 THE COURT: I understand. You had done that,
24 and I thought we were ready to go.

15:49:40 25 MR. MILANO: We are, Judge. And I don't want

Catizone - Direct (By Mr. Feran)

1 to argue it again, I just thought this might look like a
2 compromise.

3 THE COURT: I understand.

4 MR. DARKEN: I just read it over the break,
15:49:48 5 and that's why I came back. I hadn't read that middle
6 section before we broke.

7 THE COURT: I'm glad you had an opportunity, I
8 am sincerely glad you had an opportunity to do so.

9 (Proceedings had in open court:)

15:50:16 10 THE COURT: All right. Mr. Feran, you may
11 proceed.

12 Sir, you're still under oath. Do you understand?

13 THE WITNESS: Yes, sir.

14 MR. FERAN: Thank you, Your Honor.

15:50:21 15 **Q.** Sir, before the break we were talking about
16 Government's Exhibit 999-A. Is that correct Mr. Catizone?

17 **A.** Yes, sir.

18 **Q.** And this is -- and you recognize this exhibit,
19 Mr. Catizone?

15:50:31 20 **A.** Yes, I do.

21 **Q.** How are you able to do that, sir?

22 **A.** This is a document that we work collaboratively with
23 the federation on.

24 **Q.** With the federation? Who is the federation, sir?

15:50:43 25 **A.** The Federal of State Medical Boards, the organization

Catizone - Direct (By Mr. Feran)

1 that prepares this document.

2 **Q.** And when you say we, who are you referring to, who is
3 we?

4 **A.** NABP, the organization I work for.

15:50:53 5 **Q.** You stated you worked collaboratively with the two
6 organizations?

7 **A.** Yes.

8 **Q.** Can you explain that, sir?

9 **A.** Sure. Information is shared between the pharmacy
15:51:03 10 boards as well as the medical boards. That information is
11 compiled by the federation, distributed to the medical
12 boards, and we also then distribute information to the
13 pharmacy boards.

14 You'll note in the report there's a particular
15:51:16 15 notation that once a board received the letter from NABP
16 identifying the website www.myviagarascript.com that the
17 Board of Pharmacy investigated the site and sent a cease and
18 desist warning letter to Ancona Drug Solutions in Florida,
19 so there's that interaction/collaboration throughout this
15:51:37 20 document and with all the disciplinary actions.

21 **Q.** And you have drafted documents like this in the past,
22 sir?

23 **A.** Yes.

24 **Q.** And the date of this document is what, Mr. Catizone?

15:51:46 25 **A.** 2008.

Catizone - Direct (By Mr. Feran)

1 Q. And had you drafted documents similar to this prior to
2 2008?

3 A. Yeah, our clearinghouse has been in existence since
4 1940.

15:51:56 5 Q. And I don't want to go through this in great detail,
6 sir, but what's the general purpose of this document?

7 A. To inform other medical boards of actions that are
8 occurring in other states.

9 Q. Is this document disseminated, sir?

15:52:10 10 A. Yes.

11 Q. And to who, and how?

12 A. It's disseminated to all the medical boards.

13 Q. And how is it disseminated?

14 A. I'm not really sure. I think they provide it on their
15:52:21 15 website and they mail it to the medical boards. It's not a
16 document we distribute.

17 Q. Sir, I want to focus your attention to Government's
18 Exhibit 999-C.

19 MR. FERAN: Permission to approach, Your
15:52:34 20 Honor?

21 THE COURT: You may.

22 MR. FERAN: Thank you.

23 Q. Do you recognize that, sir?

24 A. Yes.

15:53:01 25 Q. Mr. Catizone, can you tell us what 999-C is?

Catizone - Direct (By Mr. Feran)

1 **A.** It's a document outlining various actions that states
2 have taken against Internet pharmacies.

3 **Q.** This document is labeled Internet Prescribing for
4 Physicians. Is that correct, sir?

15:53:43 5 **A.** Yes, it is.

6 **Q.** And on the second page of this document it states,
7 Prescriptions approved based on responses to an online
8 questionnaire. Is that correct, Mr. Catizone?

9 **A.** Yes, sir.

15:53:55 10 **Q.** And you have seen this document before, Mr. Catizone?

11 **A.** Yes, I have.

12 **Q.** And what is the purpose of this document, sir?

13 **A.** It's an information source for pharmacy boards and
14 medical boards about activities occurring in regard to
15:54:09 15 internet pharmacies.

16 **Q.** And it talks about regulatory requirements,
17 enforcement actions, and enforcement. Is that correct, sir?

18 **A.** Yes, sir.

19 **Q.** And what is, in summation, the prescription approval
15:54:23 20 based on online questionnaires, what is the summary of that,
21 sir?

22 **A.** The two conclusions are, one, that there must be a
23 face-to-face physical examination to establish a
24 relationship; and two, prescriptions based solely on
15:54:38 25 questionnaires are not valid prescriptions.

Catizone - Direct (By Mr. Feran)

1 **Q.** There's authority cited. Is that correct, sir?

2 **A.** Yes.

3 **Q.** Can you tell us about that?

4 **A.** There's authority noting individual states, as well as
15:54:47 5 the FDA and the Department of Justice, all the federal
6 agencies that I mentioned that are involved with the laws
7 and regulations.

8 **Q.** So there's the state medical board and the FDA is both
9 cited?

15:54:58 10 **A.** Yes.

11 **Q.** And it talks about a bona fide physician-patient
12 relationship?

13 **A.** Yes, sir.

14 **Q.** Mr. Catizone, I want to focus your attention to
15:55:10 15 Government 999. Sir, what is the date on the last exhibit,
16 if you would tell me, please?

17 **A.** 2004, April 6.

18 **Q.** 999, Mr. Catizone, for the record, I'm handing you
19 999. Are you familiar with that, sir?

15:55:32 20 **A.** Yes, I am.

21 **Q.** And can you tell us, Mr. Catizone, how you are
22 familiar with that?

23 **A.** The document is again produced by the Federation of
24 State Medical Boards, it's entitled the Model Guidelines For
15:55:46 25 the Appropriate Use of the Internet in Medical Practice.

Catizone - Direct (By Mr. Feran)

1 It's a document that was prepared by the federation in 2002,
2 and a document that we worked with the federation on and
3 submitted comments to them.

4 **Q.** And what is the purpose of this document,
15:55:58 5 Mr. Catizone?

6 **A.** It was to provide guidance to physicians and to
7 medical boards about the practice of Internet pharmacy and
8 telemedicine, and how physicians should practice that
9 particular niche.

15:56:13 10 **Q.** Sir, did you participate in the drafting of this
11 document?

12 **A.** Participated in commenting on this document.

13 **Q.** And in relation to commenting on this document, sir,
14 can you tell us about how you commented on this document?
15:56:26 15 What does that mean?

16 **A.** Sure. The federation sent to us a draft, and I
17 personally reviewed the draft and prepared comments back
18 based upon the regulations and requirements and pharmacy
19 boards, and sent that information back to the federation, as
15:56:39 20 well as giving our opinion on behalf of the association as
21 to what we felt would be suitable standards of practice
22 based upon pharmacy standards, laws, and regulations.

23 **Q.** And Mr. Catizone, are you scheduled to testify
24 relating to this document?

15:56:51 25 **A.** I'm sorry, I didn't hear the question.

Catizone - Direct (By Mr. Feran)

1 **Q.** Are you scheduled to give commentary on this document,
2 sir?

3 **A.** No.

4 **Q.** Sir, on the third page, Model Guidelines for the
15:57:04 5 Appropriate Use of the Internet in Medical Practice, do you
6 see that?

7 **A.** Yes, sir.

8 **Q.** The page that's numbered page 2, do you see that, sir?

9 **A.** Yes.

15:57:09 10 **Q.** All right. It's the second paragraph. It states,
11 "The board recognizes." Do you see that, sir?

12 **A.** Yes, I do.

13 **Q.** Can you read that, Mr. Catizone?

14 **A.** "Recognizes that the Internet offers potential
15:57:21 15 benefits in the provision of medical care. The appropriate
16 application of this technology can enhance medical care by
17 facilitating communication with physicians and other health
18 care providers, refilling prescriptions, obtaining
19 laboratory results, scheduling appointments, monitoring
15:57:38 20 chronic conditions, providing health care information, and
21 clarifying medical advice. However, it is the expectation
22 of the board that e-mail and other electronic communications
23 and interactions between the physician and patient should
24 supplement and enhance but not replace crucial interpersonal
15:57:58 25 interactions that create the very basis of the

Catizone - Direct (By Mr. Feran)

1 physician-patient relationship."

2 **Q.** Can you continue, sir?

3 **A.** "The board has developed these guidelines to educate
4 licensees as to the appropriate use of the Internet medical
15:58:08 5 practice. The (name of the board) has committed to assuring
6 patient access to the convenience and benefits afforded by
7 the Internet while promoting the responsible practice of
8 medicine by physicians."

9 **Q.** And it talks in the last paragraph, sir, if you could
15:58:22 10 read that?

11 **A.** "It is the expectation of the board that physicians
12 who provide medical care electronically or otherwise
13 maintain a high degree of professionalism and should place
14 the welfare of patients first, maintain acceptable standards
15:58:35 15 of practice, adhere to recognized ethical codes governing
16 the medical profession, properly supervise physician
17 extenders, and protect patient confidentiality."

18 **Q.** There is a cite at the bottom of that, sir. Do you
19 see that at the bottom of the page? It's referenced on the
15:58:47 20 bottom of page 2. Do you recognize that cite?

21 **A.** Yes.

22 **Q.** Tell us about that.

23 **A.** It's referencing the American Medical Association's
24 report of their Council on Medical Services.

15:58:59 25 **Q.** Let's talk -- if you can flip it over to Section 3,

Catizone - Direct (By Mr. Feran)

1 Mr. Catizone. It says Appropriate Physician-Patient
2 Relationship. Do you see that, sir?

3 **A.** Yes, I do.

4 **Q.** Mr. Catizone, can you please read Section 3?

15:59:08 5 **A.** "The health and well-being of patients depends upon a
6 collaborative effort between physician and patient. The
7 relationship between physician and patient is complex and is
8 based on a mutual understanding between physician and
9 patient of the shared responsibility for the patient's
15:59:24 10 health care. Although the board recognizes that it may be
11 difficult in some circumstances, particularly in an online
12 setting, to define precisely the beginning of the
13 physician-patient relationship, it tends to begin when an
14 individual seeks assistance from a physician with a
15:59:41 15 health-related matter for which the physician may provide
16 assistance. However, the relationship is clearly
17 established when the physician agrees to undertake diagnosis
18 and treatment of the patient and the patient agrees, whether
19 or not there has been a personal encounter between the
15:59:57 20 physician or other supervised health care practitioner and
21 the patient."

22 **Q.** The next paragraph, sir, says?

23 **A.** "The physician-patient relationship is fundamental to
24 the provision of acceptable medical care. It is the
16:00:09 25 expectation of the board that physicians recognize the

Catizone - Direct (By Mr. Feran)

1 obligations, responsibilities, and patient rights associated
2 with establishing and maintaining an appropriate
3 physician-patient relationship whether or not interpersonal
4 contact between physician and patient has occurred."

16:00:23 5 **Q.** And, sir, this is referenced in footnote number 2. Is
6 that correct?

7 **A.** Yes, it is.

8 **Q.** And what is footnote number 2?

9 **A.** The American Medical Association Council on Ethical
16:00:33 10 and Judicial Affairs, fundamental elements of a
11 patient-physician relationship.

12 **Q.** And this was cited, Mr. Catizone?

13 **A.** Yes.

14 **Q.** Let's go, sir, if we could, to Section 5. What is
16:00:49 15 that called?

16 **A.** Guidelines for the Appropriate Use of the Internet
17 Medical Practice.

18 **Q.** And can you read the first two paragraphs, the
19 preamble and the first two paragraphs, sir?

16:01:02 20 **A.** "The board has adopted the following guidelines for
21 physicians utilizing Internet and delivery of patient care.
22 A documented patient evaluation, including history and
23 physical evaluation, adequate to establish diagnosis and
24 identify underlying conditions, and/or contraindications to
16:01:21 25 the treatment recommended provided, must be obtained prior

Catizone - Direct (By Mr. Feran)

1 to providing treatment, including issuing prescriptions
2 electronically or otherwise.

3 "Treatment: Treatment and consultation
4 recommendations made in an online setting, including issuing
16:01:38 5 a prescription via electronic means, will be held to the
6 same standards of appropriate practice as those in
7 traditional face-to-face settings. Treatment, including
8 issuing a prescription, based solely on an online
9 questionnaire or consultation does not constitute an
16:01:57 10 acceptable standard of care."

11 **Q.** Sir, let's talk about pharmacies located in one state
12 and dispensing in another state, if we could. And if a
13 pharmacy, for example, is located in Florida and wanted to
14 dispense controlled substances in Ohio, can you tell us the
16:02:31 15 steps that would be required of that Florida pharmacy?

16 **A.** Sure. The pharmacy would have to meet all the
17 requirements of a license in the state where it's located,
18 as well as apply for licensure or registration in any of the
19 states in which they were going to be dispensing medication,
16:02:48 20 and comply with the laws and regulations of that state, as
21 well.

22 **Q.** So for example, Mr. Catizone, a Florida pharmacy
23 dispensing in Ohio, where would that Florida pharmacy have
24 to be licensed?

16:03:00 25 **A.** In both states, Florida and Ohio.

Catizone - Direct (By Mr. Feran)

1 **Q.** How would an out-of-state pharmacist go about
2 obtaining an Ohio registration?

3 **A.** They'd have to complete the application process
4 similar to a traditional Board of Pharmacy.

16:03:17 5 **Q.** Can you explain, sir, in the simplest terms?

6 **A.** They obtain an application from the Board of Pharmacy,
7 complete that application, and then the Board of Pharmacy
8 would either personally inspect that pharmacy or ask the
9 Board of Pharmacy where it was located to inspect that
16:03:33 10 pharmacy, or utilize a recent inspection form from the Board
11 of Pharmacy where it was located, in order to determine
12 whether it should be licensed or not.

13 **Q.** In relation to this case, Mr. Catizone, did Vinesh
14 Darji have a license to distribute controlled substances in
16:03:48 15 the state of Ohio?

16 **A.** He didn't have a license as a pharmacy at all with
17 Ohio.

18 **Q.** Sir, you stated that you have reviewed various
19 documents in the case file regarding the issue we're here on
16:04:09 20 today. Do you have an opinion relating to Vinesh Darji
21 filling prescriptions, and did he act outside the usual
22 course of professional practice?

23 **A.** Based upon all the information I reviewed, which were
24 the existing standards of practice, the requirements that a
16:04:28 25 pharmacist has to follow, the prescription information, the

Catizone - Direct (By Mr. Feran)

1 undercover purchases, it's my opinion that the pharmacy did
2 not comply and the pharmacy operated outside standards of
3 practice, and did not meet the standards of care that
4 pharmacies and pharmacists are required to meet.

16:04:47 5 **Q.** And Mr. Catizone, let's go through this, and I want
6 you to explain to the jury what you base your opinion on.
7 Can you tell us, sir, some of the criteria that you have
8 used to reach that opinion?

9 **A.** The first was whether or not a valid prescription was
16:05:07 10 for the pharmacy to dispense that medication.

11 Looking at how those prescriptions were generated, the
12 doctors involved did not conduct the face-to-face physical
13 examination. There was not a bona fide relationship.
14 Review of the purchase orders indicated that many times it
16:05:26 15 was not even the doctor that talked to the patient, but a
16 customer service representative. And then there was no
17 follow up by a doctor directly with the patient, and that
18 the doctor was located in Puerto Rico or other states, and
19 then providing prescriptions for patients across the United
16:05:47 20 States where no relationship existed.

21 **Q.** Stop right there, Mr. Catizone. You stated a
22 legitimate doctor-patient relationship did not exist?

23 **A.** Correct.

24 **Q.** Can you explain that, sir?

16:05:56 25 **A.** That was what we talked about earlier, that there was

Catizone - Direct (By Mr. Feran)

1 a medication history taken by the doctor, that there was a
2 physical examination, and that there was no relationship
3 between the diagnosis and the medication prescribed. I
4 didn't find any of that in any of the information that I
16:06:11 5 reviewed.

6 **Q.** You talked, sir, about -- you mentioned Puerto Rico
7 and other states. Can you be more specific? Can you
8 explain what you mean by that, sir?

9 **A.** There was a doctor that was authorizing prescription
16:06:22 10 orders who was based in Puerto Rico for patients across the
11 country, that the pharmacy then would select those orders
12 and dispense those orders without affirming that there was a
13 valid relationship, and without that pharmacy having any
14 relationship with that patient or with that doctor, as well.

16:06:37 15 **Q.** Where was the pharmacy located, Mr. Catizone?

16 **A.** The pharmacies were located in Florida.

17 **Q.** And were there multiple pharmacies, sir?

18 **A.** Yes, there were.

19 **Q.** And where were the pharmacies, plural, located?

16:06:49 20 **A.** They were located in close proximity to each other
21 in -- I can't recall the exact cities or locations.

22 **Q.** The pharmacy is in the state of Florida, pharmacies --
23 strike that -- and the doctor is in Puerto Rico. Did
24 this -- can you comment on this? Was it significant at any
16:07:09 25 point?

Catizone - Direct (By Mr. Feran)

1 **A.** Yes. That's one of the red flags that even the
2 Florida regulations mention about the suspicion about the
3 validity of a prescription, and that's a red flag that for
4 us helps determine whether or not it's a rogue or illegal
16:07:24 5 pharmacy.

6 **Q.** Did the type of controlled substance play into your
7 analysis, sir?

8 **A.** Yes. Looking at the products that were dispensed,
9 they were primarily the hydrocodone products, significant
16:07:38 10 quantities of hydrocodone products far exceeding quantities
11 that are normally dispensed by other Internet pharmacies and
12 traditional brick and mortar pharmacies, and also the
13 distribution of those products, the same quantities, same
14 strengths, to different patients and across the country.

16:07:56 15 **Q.** Is that a red flag, sir?

16 **A.** Yes.

17 **Q.** Why?

18 **A.** Again, a patient that's being treated for pain or for
19 these medications, it's going to be a very limited time
16:08:06 20 period. Generally you want to have just a few weeks of
21 treatment, because if a patient takes a hydrocodone product
22 every day for three weeks they begin to develop an addiction
23 generally. And if they continue after that time period, if
24 they try to stop the medication they'll experience
16:08:24 25 withdrawal effects from that medication.

Catizone - Direct (By Mr. Feran)

1 MR. GORENCE: Your Honor, I'm going to object
2 on foundation. I haven't seen anything that he's a
3 toxicologist, and he may have the basis for that, but I'd
4 ask that a foundation be laid to be able to venture that
16:08:38 5 opinion. That's not in his report, so I object until
6 there's an appropriate foundation.

7 MR. FERAN: I'll be happy to lay a foundation.

8 **Q.** Mr. Catizone, are you familiar with the
9 pharmalogic -- pharm -- I'm having a hard time
16:08:52 10 here -- pharmalogic -- pharmacology of hydrocodone?

11 I'm going to get this right, Judge.

12 **A.** Yes.

13 **Q.** First of all, how do you pronounce that word?

14 **A.** Pharmacology.

16:09:02 15 **Q.** Thank you. I'm a lawyer, not a pharmacist. Thank
16 you, Mr. Catizone. Can you tell us how you are familiar
17 with that?

18 **A.** Pharmacists are required to know the pharmacology of
19 drugs, the composition of the drug, what it's used for, the
16:09:15 20 side effects it may have, and the potential dangers that
21 they present to a patient.

22 **Q.** Are you aware of this, sir?

23 **A.** Yes.

24 **Q.** How are you aware?

16:09:23 25 **A.** Again, it's part of the training that every pharmacist

Catizone - Direct (By Mr. Feran)

1 receives and is required to know.

2 **Q.** Tell us about the pharmacology of hydrocodone.

3 **A.** I think I did just a few minutes ago about the fact

4 that it's highly addictive after a few weeks. If the

16:09:43 5 patient is not taken off the medication they could develop

6 significant addiction and even suffer withdrawal effects if

7 the medication is stopped immediately.

8 **Q.** You talked, Mr. Catizone, about distribution patterns
9 raising a red flag.

16:09:57 10 **A.** Yes, the quantity.

11 **Q.** Can you explain that, sir?

12 **A.** The quantities of hydrocodone dispensed by the

13 pharmacies that I reviewed far exceeded state averages as

14 well as national levels in the reports that were provided by

16:10:11 15 the government, and these were significant levels. They

16 weren't just a few prescriptions, they were very

17 significant. And again, the mix of products that they

18 dispensed was significantly different than what a

19 traditional pharmacy would dispense, and that the vast

16:10:27 20 majority of products were controlled substances.

21 **Q.** In a traditional pharmacy, sir, you stated what
22 percentage of a product is a controlled substance?

23 **A.** About 8 to 10 percent.

24 **Q.** 8 to 10 percent. And Mr. Darji 's three pharmacies,

16:10:40 25 do you remember the percentages that were controlled

Catizone - Direct (By Mr. Feran)

1 substances?

2 **A.** Percentages were sometimes 70, 80 percent of the
3 prescriptions.

4 **Q.** Was there a mixture of controls with noncontrols being
16:10:56 5 dispensed, sir?

6 **A.** Yes, sir.

7 **Q.** Did this cause any red flag?

8 **A.** What was interesting in one of the statements that I
9 reviewed and one of the reports, one of the telephone

16:11:06 10 conversations that was recorded, is that there was the use

11 of the noncontrolled substance medications, like ibuprofen

12 and other products, as a way of making sure, trying to

13 insure that if a law enforcement official reviewed the

14 pharmacy records they would see that there was a mixture of

16:11:25 15 controlled and noncontrolled, and it would change those

16 ratios or change those percentages.

17 And it was a statement made that said, let's use the

18 controlled substances and then explain that the

19 noncontrolled substances would be used if there was a

16:11:38 20 breakthrough pain in the patient, which is the complete

21 opposite of therapy that are taught to pharmacists, and that

22 you generally use noncontrolled substances for pain and then

23 use the controlled substances for breakthrough pain so that

24 you avoid the patient becoming addicted or abusing the

16:11:58 25 medications, but at the same time you control the pain.

Catizone - Direct (By Mr. Feran)

1 So the noncontrolled substances were ordered and used
2 to try and disguise the ordering quantities of the
3 controlled substances.

4 **Q.** Based on your training and experience, Mr. Catizone,
16:12:11 5 is this indicative of anything?

6 **A.** It's indicative of an operation that is trying to
7 traffic or distribute controlled substances without a
8 legitimate prescription, and not in the best interests of
9 the patients, because there's no valid relationship between
16:12:27 10 the doctor and patient or between the patient and
11 pharmacist.

12 **Q.** You looked at the raw numbers being distributed by the
13 three Darji pharmacies; is that correct, sir?

14 **A.** Yes, sir.

16:12:35 15 **Q.** Do you know the names of these pharmacies by chance?

16 **A.** I believe it was Medicom, Medicine Shoppe, and
17 Vin-Kash.

18 **Q.** The numbers by themselves, the raw numbers, are they
19 normal, sir?

16:12:48 20 **A.** As I mentioned, they're very significant and far
21 exceed quantities of any traditional pharmacy. It even
22 exceeds state and national numbers.

23 **Q.** And just so we're clear, we're talking about the
24 distribution of hydrocodone. Is that correct, sir?

16:13:00 25 **A.** Yes, sir.

Catizone - Direct (By Mr. Feran)

1 Q. Mr. Catizone, in preparation for your testimony here
2 today are you familiar with the term dispensing fee?

3 A. Yes, I am.

4 Q. Can you tell us, sir, what a dispensing fee is?

16:13:13 5 A. It's a fee that's usually added on to the prescription
6 to compensate the pharmacist for their professional
7 services, what they do in terms of drug utilization review
8 and making sure the prescription is appropriate.

9 Q. And Mr. Catizone, based on your professional
16:13:27 10 experience and your expertise, are you familiar, sir, with
11 typical dispensing fees for controlled and noncontrolled
12 substances?

13 A. Yes, sir.

14 Q. Can you tell us about that, Mr. Catizone?

16:13:37 15 A. Sure. The usual dispensing fee is not differentiated
16 between a controlled substance or noncontrolled
17 substance --

18 Q. Can you stop right there, sir? So if you distributed
19 a controlled and a noncontrolled, it's the same fee?

16:13:48 20 A. Yes.

21 Q. Can you tell us about that, sir? Why is that?

22 A. It's based upon the plan that the pharmacy agrees to,
23 and there's just a set professional fee for the dispensing
24 of those prescription products, and it generally will range
16:14:01 25 anywhere between 50 cents to perhaps two and a half dollars.

Catizone - Direct (By Mr. Feran)

1 The professional fees are not significant for pharmacies.

2 **Q.** When you say 50 cents to two and a half dollars,

3 Mr. Catizone, for what? What does that mean?

4 **A.** Some plans may reimburse the pharmacist 50 cents per

16:14:20 5 prescription whether it's controlled or noncontrolled, other

6 plans may reimburse them \$2.50 for every prescription

7 whether it's controlled or noncontrolled. There's no

8 differentiation within a plan for a controlled substance

9 versus a noncontrolled.

16:14:33 10 **Q.** Is this putting the pills in the bottle, is this what

11 we're talking about here, sir?

12 **A.** Well, reviewing the prescription beforehand, making

13 sure it's appropriate, counseling the patient, all those

14 activities for \$2.50 or maybe \$.50.

16:14:47 15 **Q.** And how did Mr. Darji's dispensing fees relate to this

16 cost average, sir?

17 **A.** The dispensing fees again did not fit into any of the

18 plans, any of the dispensing fees that I'm aware of or have

19 seen in reviewing pharmacies. There was a \$20 fee for

16:15:04 20 controlled substances and a \$4 fee for noncontrolled

21 substances. And again, I've not seen that dispensing fee in

22 any insurance plan, any pharmacy plan, that I've ever

23 reviewed.

24 **Q.** When looking at the records, Mr. Catizone, did you

16:15:23 25 look at various prescriptions?

Catizone - Direct (By Mr. Feran)

1 **A.** Yes, sir.

2 **Q.** And I want to talk about various addresses that were
3 noted. Can you tell us about that, sir?

4 **A.** Yeah. I observed with the prescriptions that
16:15:39 5 were -- there were several instances where multiple patients
6 were dispensed prescriptions, and both patients resided at
7 the same address but had different names. That again would
8 be an immediate red flag for the pharmacist.

9 In one case there were I believe 30 patients utilizing
16:15:58 10 the same address, receiving the same controlled substance,
11 the same quantity, the same strength. Again, for a
12 pharmacist that would be an immediate red flag to question
13 why all these individuals were residing at the same address
14 and why they were all receiving the same controlled
16:16:17 15 substance, the same pain medication, from the same doctor,
16 with the same quantities and strengths and dosage.

17 Another instance, there were 55 patients prescribed
18 prescriptions at the same address, and in those two cases
19 one of the addresses even was listed as Extreme Video, which
16:16:39 20 appeared to be a business address. And again, as a
21 pharmacist responsibility warning signs, there should have
22 been some investigation, some action taken on those
23 prescriptions.

24 **Q.** Sir, you stated there were 30 patients at one address.
16:16:54 25 Is that 30 scripts at one address?

Catizone - Direct (By Mr. Feran)

1 **A.** Yes.

2 **Q.** Were certain patients having more than one script
3 delivered to an address?

4 **A.** Yes. There were some patients that were receiving 10
16:17:07 5 to 12 to 14 prescriptions on a regular basis for the pain
6 medication, which again is outside of the dosing parameters.
7 As we mentioned, they should have been on for a short term,
8 just a few weeks. Again, that would have been another
9 warning sign for the pharmacist to investigate further to
16:17:24 10 find out what was going on with this patient and why they
11 needed that therapy for so long.

12 MR. FERAN: Miss Johnson, if you could pull up
13 433-A as in Apple, please.

14 **Q.** Do you recognize this, Mr. Catizone?

16:17:36 15 **A.** Yes.

16 **Q.** Thank you, Miss Johnson. And what do you recognize
17 this to be?

18 **A.** This is one of the patients that received multiple
19 prescriptions.

16:17:47 20 **Q.** And what address was this received at, sir?

21 **A.** A few years ago I could read it a lot clearer, but I
22 think it is 8290 Roswell Road, as I remember.

23 **Q.** I'm sorry, sir?

24 **A.** 8290 Roswell Road. Thank you.

16:18:04 25 **Q.** Thank you, sir. And the patient's name is Laura

Catizone - Direct (By Mr. Feran)

1 Keeley?

2 **A.** Correct.

3 **Q.** And the date on this is? Miss Johnson, if you could
4 scroll down. Thank you.

16:18:14 5 **A.** May 2006, May 1.

6 MR. FERAN: 433-B, Miss Johnson.

7 **Q.** The patient name and address?

8 **A.** Same patient, Laura Keeley, same address.

9 **Q.** And the date on this, sir?

16:18:30 10 **A.** May 30th, 2006.

11 **Q.** And C? Would you tell us about this, sir?

12 **A.** The same patient, same address, same 90 tablets. And
13 the date -- if you could scroll down, please.

14 **Q.** Scroll down, Miss Johnson?

16:18:52 15 **A.** July 2006.

16 **Q.** E, Ms. Johnson?

17 **A.** Again, the same patient, same address, same quantity.
18 And this prescription was issued in August.

19 **Q.** G, Miss Johnson?

16:19:15 20 **A.** Same as before. You can see they're being written for
21 the same patient, same address, same quantities, and just
22 about on a one monthly basis, sometimes more.

23 **Q.** K? Can you tell us what this is, sir?

24 **A.** The same; another prescription, the same person, same
16:19:47 25 address.

Catizone - Direct (By Mr. Feran)

1 Q. There's a different doctor noted on this one, is there
2 not, sir?

3 A. Yes.

4 Q. Dr. Gordon?

16:19:59 5 A. Yes.

6 Q. Is that indicative of anything?

7 A. The fact that, again, there's a different doctor was
8 one of the warning signs that Florida had mentioned, a
9 patient receiving the same medication from different

16:20:11 10 doctors. That was in the Florida regulation, something a
11 pharmacist would need to investigate.

12 Q. Continue to Q, Miss Johnson. What is this? Tell us
13 what this is, Mr. Catizone.

14 A. Again, a prescription for Laura Keeley, quantity, the
16:20:35 15 date. Now it's November, and the doctor now has moved back
16 to another doctor.

17 Q. S? Can you tell us what this is, sir?

18 A. Same comments as the prior prescriptions.

19 Q. W?

16:21:01 20 A. Again, the same comments apply.

21 Q. And AA, Miss Johnson?

22 A. Again, same medication, same patient, same address.

23 Q. And there's a note on this one, Mr. Catizone. Can you
24 read that note into the record, sir?

16:21:29 25 A. Sure. It says, "Notes. Interactions, reviewed the

Catizone - Direct (By Mr. Feran)

1 medical information and spoke with patient.

2 Patient" -- sorry, I can't -- "rates pain as a 9 on a

3 1-to-10 scale. On medication patient is a 2. Patient

4 complained of head pain. Patient stated that has been on

16:21:53 5 medication before as prescribed by M.D. without side effects

6 or problems. Oriented patient about medication tolerance

7 and habit forming effect. Advised to use only" -- and then

8 the rest of it is kind of blurred, and it also talks about

9 to monitor the amount of acetaminophen, which is Tylenol.

16:22:12 10 **Q.** Is there any significance to this, Mr. Catizone?

11 **A.** One, I have not seen this type of information on

12 prescriptions in traditional or Internet pharmacies. Two,

13 if you review all the records, this same information with

14 little variance -- sometimes it may say 8 on a scale of 10

16:22:31 15 or 9 -- occurs for just about every patient, which again is

16 unusual that every single patient would have that same

17 reading, and there's a necessity to place this on the

18 prescription in order to justify that prescription.

19 **Q.** Now, we have ten prescriptions going out to Laura

16:22:52 20 Keeley at this address, correct, sir?

21 **A.** Yes.

22 **Q.** Is that a red flag?

23 **A.** It's a red flag. And if you look at the warning

24 there, the warning says that they advised the patient about

16:23:01 25 tolerance and habit forming effect, yet they've issued 90

Catizone - Direct (By Mr. Feran)

1 tablets for the patient every single month. There should
2 have been some further documentation or some annotation
3 about the discussion and why the patient is allowed to
4 continue on this for about 11 months or so.

16:23:20 5 **Q.** Miss Johnson, can you pull up 433-R. What is the name
6 on this, sir?

7 **A.** Nikisha Dawson.

8 **Q.** And what's the prescription date?

9 **A.** It looks like 12 December 2006.

16:23:40 10 **Q.** And what is the address on this one, sir?

11 **A.** The same address as Laura Keeley.

12 **Q.** And this is dated what, sir? I'm sorry.

13 **A.** December 2006.

14 **Q.** December what, sir?

16:23:52 15 **A.** 28th.

16 **Q.** S, Miss Johnson. The date on this one, sir?

17 **A.** December 28, 2006.

18 **Q.** The same as R?

19 **A.** Yes.

16:24:07 20 **Q.** And who is the person on this one?

21 **A.** Laura Keeley.

22 **Q.** Does this cause you any concern?

23 **A.** Again, as mentioned in the Florida regulations, we

24 have patients on the same day getting prescriptions from the

16:24:20 25 same doctors in different states for the same medication,

Catizone - Direct (By Mr. Feran)

1 same quantities. Doesn't seem to have a logical connection
2 to a valid relationship or to a valid diagnosis.

3 **Q.** And looking at -- I don't want to go through all of
4 these again, the 431 series, we'll just pull up one, Miss
16:24:40 5 Johnson, 431-A, and you can blow that up. The address on
6 431-A is what, sir?

7 **A.** It looks -- 585 Tahoma Drive.

8 **Q.** And in the course of your review were there a number
9 of prescriptions sent to this address?

16:25:02 10 **A.** Yes. There were over 50 for this address.

11 **Q.** Over 50 for this address?

12 **A.** Yes, sir.

13 **Q.** Would this cause you concern?

14 **A.** Significant concern.

16:25:09 15 **Q.** And why is that, sir?

16 **A.** As I mentioned earlier, to have 50 prescriptions for
17 different patients to the same address just doesn't seem
18 logical, and it would be something the pharmacist would have
19 to check. It's not something that the pharmacist would let
16:25:23 20 go by.

21 **Q.** And how would a pharmacist, Mr. Catizone, go about
22 checking this?

23 **A.** They'd have to verify each prescription with a doctor
24 and then question the patients as to why they all resided or
16:25:35 25 gave the same address, and if it was any doubt or suspicion

Catizone - Direct (By Mr. Feran)

1 in the pharmacist's mind they shouldn't fill that
2 prescription, or there should be some further evaluation or
3 reporting to law enforcement.

4 **Q.** Based on your training and experience, Mr. Catizone,
16:25:46 5 what is a reasonable refill on hydrocodone 90, how many
6 times should this occur?

7 **A.** There shouldn't be a refill unless there's a
8 significant need or some sort of chronic pain condition
9 that's well documented and treated by a pain management
16:26:00 10 specialist.

11 **Q.** Should it go on for a period of 10 refills, sir?

12 **A.** Again, based upon what the medication is intended to
13 be used for and what the warnings are, the answer is no.

14 **Q.** Sir, what do you say to a pharmacist who says, well, I
16:26:16 15 don't have the computer software to do a record check?

16 **A.** The law doesn't care whether or not in responsibility
17 to a patient whether you have a computer or manage it using
18 paper and pencil. The responsibility still exists, and the
19 pharmacist is still responsible for that care of that
16:26:29 20 patient.

21 **Q.** Let's talk about that, sir. Are you familiar with
22 chief pharmacist?

23 **A.** Yes.

24 **Q.** What is a chief pharmacist?

16:26:36 25 **A.** It's a term that varies from state to state. It may

Catizone - Direct (By Mr. Feran)

1 be the pharmacist in charge, in some states it may be the
2 chief pharmacist, it may be the responsible pharmacist.

3 Every pharmacy in every state has to have a chief
4 pharmacist, and that's the individual that's legally
16:26:51 5 responsible for executing documents, ordering controlled
6 substances, complying with the Board of Pharmacy
7 regulations, and being responsible for the entire operation
8 of dispensing of that pharmacy, the other pharmacists, and
9 any other technicians that may be used.

16:27:09 10 **Q.** And who was the chief pharmacist in this case, sir?

11 **A.** Mr. Darji.

12 **Q.** Mr. Darji?

13 **A.** Yes.

14 **Q.** And you stated he would be responsible for all aspects
16:27:22 15 of the pharmacist operations?

16 **A.** Yes, sir.

17 **Q.** Tell us what that means, all aspects. What does that
18 mean?

19 **A.** The pharmacist is responsible for making sure that all
16:27:31 20 of the laws and regulations are followed, making sure that
21 the other pharmacists are practicing in accordance with the
22 laws, and if anything happens in the pharmacy the Board of
23 Pharmacy then holds the chief pharmacist responsible for
24 those activities, whether they were directly involved or
16:27:47 25 not. It's their responsibility that the processes,

Catizone - Direct (By Mr. Feran)

1 procedures, and the personnel all fall under the charge of
2 the chief pharmacist.

3 **Q.** Are you familiar with the term pharmacy tech,
4 Mr. Catizone?

16:27:58 5 **A.** Yes.

6 **Q.** What's a pharmacy tech?

7 **A.** A tech is somebody that assists the pharmacist in the
8 practice of pharmacy. In some states they're required to be
9 registered, other states they're not. The technician can
16:28:09 10 only engage in limited activities. They're not allowed to
11 counsel patients, they're not allowed to dispense
12 medications when the pharmacist is not there. They're not
13 allowed to do anything without the direct supervision of the
14 pharmacist in terms of taking the medication off the shelf,
16:28:26 15 filling it, and then providing it to the patient. The
16 pharmacist has to oversee that entire process and is legally
17 responsible for it.

18 **Q.** So can you tell us, sir, about the interaction between
19 the chief pharmacist and the pharmacy techs? Is anybody
16:28:41 20 responsible for the pharmacy tech distribution?

21 **A.** The chief pharmacist is.

22 **Q.** What if other pharmacists are employed at a pharmacy,
23 sir, who ultimately is responsible for distribution of that
24 pharmacy?

16:28:51 25 **A.** The chief pharmacist.

Catizone - Direct (By Mr. Feran)

1 **Q.** You stated, sir, that Mr. Darji was the chief
2 pharmacist at those three pharmacies?

3 **A.** Yes, sir.

4 **Q.** Who was the owner of those pharmacies?

16:29:01 5 **A.** Mr. Darji also.

6 **Q.** We were talking, sir, about three pharmacies involved
7 here. Is that correct?

8 **A.** Yes, sir.

9 **Q.** Is this unusual?

16:29:13 10 **A.** It's not unusual for somebody to own multiple
11 pharmacies.

12 **Q.** Was the way that the pharmacies were utilized in this
13 case, did that cause you a red flag?

14 **A.** Yes.

16:29:21 15 **Q.** Can you explain that, sir?

16 **A.** Sure. The prescriptions were distributed across the
17 three pharmacies, not based upon the patient relationships
18 or the physician relationships. From the information, they
19 were dispersed to conceal the distribution of controlled
16:29:39 20 substances by the pharmacy so that one pharmacy didn't have
21 totals that were so high that it would draw red flags or
22 draw the attention of law enforcement, so the prescriptions
23 then were dispersed across all three.

24 **Q.** With Mr. Darji being the owner of these pharmacies,
16:29:56 25 Mr. Catizone, can you tell us what the owner's obligations

Catizone - Direct (By Mr. Feran)

1 are?

2 **A.** The owner has the same responsibilities as the
3 pharmacist in terms of being responsible for distribution
4 and compliance with the laws. If there's a problem with the
16:30:10 5 clinical aspect of it where the pharmacist wasn't competent,
6 that would fall on the pharmacist, but the owner then would
7 also be responsible for hiring that pharmacist and not
8 making sure that the pharmacist was competent.

9 **Q.** You talked, Mr. Catizone, about the three pharmacies
16:30:24 10 and moving things around. Are you familiar with the term
11 spreading, spreading prescriptions?

12 **A.** In the context of the case, yes.

13 **Q.** Can you tell us what spreading means, sir?

14 **A.** That's what I just explained, where they were trying
16:30:37 15 to spread the controlled substance prescriptions among the
16 three so that not one of the pharmacies reflected the total
17 number of controlled substances that were being dispensed.

18 **Q.** Sir, let's talk about the actual script itself.
19 E-signatures, electronic signatures, can you discuss that
16:30:59 20 with us, please? Are they permitted on prescriptions?

21 **A.** On non --

22 **Q.** On controlled substance prescriptions are electronic
23 signatures during the time frame between October of 2005 and
24 February of 2009?

16:31:15 25 **A.** The DEA issued a guidance document that said

Catizone - Direct (By Mr. Feran)

1 prescriptions can only be received via fax or oral, which
2 means over the phone or directly from the prescriber, and
3 that prescriptions transmitted via the Internet were not
4 acceptable.

16:31:31 5 **Q.** So are e-signatures valid, sir?

6 **A.** No.

7 **Q.** Let's talk about the term spot checking. Have you
8 heard that in connection with this case?

9 **A.** Yes.

16:31:43 10 **Q.** What do you understand spot checking to be?

11 **A.** Spot checking in this case was that the pharmacist
12 would spot check prescriptions or look at particular orders
13 to make sure that those -- or to try to determine that they
14 were valid.

16:31:57 15 Spot checking doesn't exist in pharmacy in that
16 regard. It may exist in the manufacturing process, where
17 you may spot check products to make sure they're all being
18 made the same. Every single prescription requires the
19 pharmacist to check it, because it would be hard to say to a
16:32:12 20 patient, I'm sorry, I spot checked the prescription before
21 you and that was right, and your prescription was wrong, but
22 I didn't check that prescription, and therefore the
23 consequences you suffer are not my fault. The pharmacist
24 has a responsibility to check every single prescription to
16:32:27 25 make sure it's correct.

Catizone - Direct (By Mr. Feran)

1 Q. And does this include controlled and noncontrolled
2 substances, sir?

3 A. Any prescription that the pharmacist dispenses,
4 controlled, noncontrolled.

16:32:41 5 MR. FERAN: Miss Johnson, if you could put up
6 Government's 701.

7 Q. Mr. Catizone, have you seen Government's 701 before?

8 A. Yes, I have.

9 Q. Did you analyze this prior to coming to court, sir?

16:33:00 10 A. Yes. I spoke about this earlier, about how the
11 quantities dispensed by these pharmacies were significantly
12 higher than --

13 MR. DARKEN: Your Honor, may I approach?

14 THE COURT: Sure.

16:33:10 15 (Proceedings had at side-bar:)

16 MR. DARKEN: Your Honor, I'm going to object
17 to this line of questioning and to any questioning about his
18 volume of scripts by doctor. This is the two-page report we
19 got, it has nothing, absolutely nothing about any
16:33:50 20 conclusions about volume of prescriptions in 701, or about
21 anything about the number of prescriptions approved by any
22 doctor in any time period.

23 MS. LUTZKO: Your Honor, if I may, the fact

24 that we gave these materials to the defendant was the

16:34:10 25 subject of Mr. -- I think it was Mr. Milano's request at the

Catizone - Direct (By Mr. Feran)

1 very beginning of the trial before we began, when we sat
2 down and we did provide them with a letter of all the
3 materials that were viewed, and that this ARCOS data was
4 among the other things that the defendants were provided
16:34:28 5 that Mr. Catizone reviewed.

6 MR. DARKEN: Your Honor, Miss Lutzko is
7 conflating two things. They have an obligation to give us
8 the list of what was reviewed, which they did belatedly, at
9 Mr. Milano's request, but they have an obligation under Rule
16:34:44 10 16 to give us a written report that lays out the basis of
11 the opinions.

12 What was given to us was what he reviewed, you know,
13 in September late, but the two-page report is the basis for
14 his opinion. Anything outside the scope of that is beyond
16:35:02 15 Rule 16. I object.

16 THE COURT: Okay. Let me just be clear. The
17 question was raised in regard to whether what had been
18 turned over by the government was adequate relative to the
19 witness. The government then I thought engaged in
16:35:30 20 discussion where the government was going to turn over the
21 materials that were underlaying his opinion. That's what I
22 thought the idea was, to give him what you have, which I
23 think they did that, right?

24 MS. LUTZKO: Your Honor, if I may, we'll move
16:35:44 25 on. We'll just keep going.

Catizone - Direct (By Mr. Feran)

1 THE COURT: Okay.

2 (Proceedings had in open court:)

3 BY MR. FERAN:

4 **Q.** Mr. Catizone, can you describe the volume of
16:36:13 5 hydrocodone distributed by the three Vinesh Darji
6 pharmacies?

7 MR. DARKEN: Same objection, Your Honor.

8 THE COURT: Come back up here.

9 (Proceedings at side-bar:)

16:37:57 10 THE COURT: Let me start backwards. What is
11 the government's response to the objection?

12 MS. LUTZKO: Your Honor, I think it's
13 absolutely appropriate, but you know, we have had another
14 witness testify about these documents, so I think we can
16:38:11 15 just move on.

16 THE COURT: Okay.

17 (Proceedings had in open court:)

18 THE COURT: You may proceed.

19 MR. FERAN: Thank you, Your Honor.

16:38:36 20 **Q.** Mr. Catizone, based on your analysis of the documents
21 provided to you, do you have an opinion regarding what was
22 the goal of Mr. Darji and this organization?

23 **A.** From the information I received, that it appeared to
24 be a goal of distributing controlled substances for profit,
16:39:07 25 particularly the hydrocodone products. I could not find any

Catizone - Cross (By Mr. Darken)

1 determination of a valid prescription, any valid
2 patient-doctor relationship, any patient care aspects of it.
3 Simply a means of distributing controlled substances for
4 profit.

16:39:27 5 MR. FERAN: Your Honor, I have -- one second,
6 Judge.

7 **Q.** And was this done, sir, in the usual course of
8 professional practice?

9 **A.** No, it wasn't.

16:39:42 10 MR. FERAN: Thank you, Judge. No further
11 questions.

12 THE COURT: All right. Mr. Darken?

13 CROSS-EXAMINATION OF CARMEN CATIZONE

14 BY MR. DARKEN:

16:40:46 15 **Q.** Good afternoon, sir.

16 **A.** Good afternoon.

17 **Q.** In connection with your testimony in this case, you
18 wrote a two-page report dated December 17, 2008; correct?

19 **A.** Yes, sir.

16:41:02 20 **Q.** Were you ever shown any records, medical records,
21 seized from Vinesh Darji's Medicine Shoppe and/or Medicom
22 Pharmacy?

23 **A.** No, sir.

24 **Q.** Were you aware that he had his pharmacist sample
16:41:38 25 medical records off the USMeds website on a sample basis?

Catizone - Cross (By Mr. Darken)

1 Did you know that?

2 **A.** Yes, sir.

3 **Q.** How did you know that?

4 **A.** That was the spot checking that was in the documents,
16:41:46 5 sir.

6 **Q.** Okay. And what documents are you referring to?

7 **A.** The reports provided to me by the government on the
8 interviews.

9 **Q.** All right. Now, when I go into Marc's Pharmacy here
16:42:05 10 with a prescription for controlled substances they don't
11 make me bring my medical records, do they?

12 **A.** No, sir.

13 **Q.** And they don't check my medical records, right?

14 **A.** No, sir.

16:42:14 15 **Q.** Okay. But you know that Vinesh Darji was sampling
16 medical records because you've been told that, right?

17 **A.** Yes, sir.

18 **Q.** Okay. Now, sampling medical records doesn't
19 mean -- it's not the same thing as spot checking
16:42:32 20 prescriptions, is it?

21 **A.** I'm not familiar with the sampling of the medical
22 records, so I connoted it to spot checking prescriptions. I
23 can't testify if it's the same or not, sir.

24 **Q.** Okay. Well, a pharmacist has no absolute duty to
16:42:53 25 review medical records, correct?

Catizone - Cross (By Mr. Darken)

1 **A.** Correct, sir.

2 **Q.** In fact, most pharmacists for most patients never see
3 the patient's medical record for a prescription, correct?

4 **A.** Correct.

16:43:09 5 **Q.** All right. Let's talk about your background a little
6 bit. You gave a course for the DEA in May of 2011, correct?

7 **A.** Yes, sir.

8 **Q.** You gave a course for the DEA in February of 2011,
9 correct?

16:43:24 10 **A.** Yes, sir.

11 **Q.** You gave a course for the DEA in January of 2010,
12 correct?

13 **A.** Yes, sir.

14 **Q.** Okay. The DEA wasn't paying you for your time for
16:43:38 15 those courses, were they?

16 **A.** No, sir.

17 **Q.** You were being paid by your employer?

18 **A.** Yes, sir.

19 **Q.** You're paid \$400,000 a year; is that correct?

16:43:48 20 **A.** Approximately, sir, yes.

21 **Q.** Well, what is it?

22 **A.** I believe it's like 450,000, sir.

23 **Q.** \$450,000. Okay. It was 400,000 a few years ago when
24 you testified at trial as a government witness, correct?

16:44:06 25 **A.** Yes, sir.

Catizone - Cross (By Mr. Darken)

1 **Q.** When did you get the \$50,000 raise?

2 **A.** Over the past two years.

3 **Q.** Okay. Now, you testified for the Department of
4 Justice in a case in San Francisco in February 2012,
16:44:25 5 correct?

6 **A.** Yes, sir.

7 **Q.** You testified for the Department of Justice in a case
8 in Boston in January 2012, correct?

9 **A.** Yes, sir.

16:44:32 10 **Q.** You testified at a case for the Department of Justice
11 in Beaumont, Texas, in June 2010; is that correct?

12 **A.** Yes, sir.

13 **Q.** Did Dr. Nelson -- do you know Dr. Nelson from Utah?

14 **A.** I don't recall, sir.

16:44:47 15 **Q.** Okay. You testified for the Department of Justice at
16 a case in the Western District of Missouri in June of 2010;
17 is that right?

18 **A.** Yes, sir.

19 **Q.** You testified for the government in Charlotte, North
16:45:04 20 Carolina, in August 2009; is that correct?

21 **A.** Yes, sir.

22 **Q.** You testified for the government in Orlando, Florida,
23 in April of 2009; is that correct?

24 **A.** Yes, sir.

16:45:14 25 **Q.** You testified for the government in the Eastern

Catizone - Cross (By Mr. Darken)

1 District of New York in the Brooklyn area in November 2008;
2 is that correct?

3 **A.** Yes, sir.

4 **Q.** You testified for the government in another case in
16:45:27 5 the Eastern District of New York in October of 2008; is that
6 correct?

7 **A.** Yes, sir.

8 **Q.** You testified for the government in Maryland in July
9 of 2008; is that correct?

16:45:37 10 **A.** Yes, sir.

11 **Q.** And you testified for the government in Minnesota in
12 November of 2006; is that correct?

13 **A.** Yes, sir.

14 **Q.** How many times have you testified for a defendant?

16:45:50 15 **A.** In administrative hearings, probably about 20 times,
16 sir. Nothing in court.

17 **Q.** How about in criminal cases?

18 **A.** No criminal cases, sir.

19 **Q.** You testified in response to Mr. Feran about red
16:46:25 20 flags. Do you remember that testimony?

21 **A.** Yes, sir.

22 **Q.** Now, red flags are a matter of your opinion, correct?

23 **A.** Yes, sir.

24 **Q.** Mr. Feran asked you about Mr. Darji's volume of
16:46:48 25 controlled substances, and you indicated that was a red

Catizone - Cross (By Mr. Darken)

1 flag, correct?

2 **A.** Yes, sir.

3 **Q.** Is that red flag in and of itself sufficient to
4 indicate any type of abuse in this case?

16:47:01 5 **A.** No, sir.

6 **Q.** And you noted that for Mr. Feran that some of the
7 prescriptions were written by a doctor in Puerto Rico,
8 correct?

9 **A.** Yes, sir.

16:47:13 10 **Q.** Is the fact that the doctor was in Puerto Rico and the
11 patients were somewhere else sufficient in and of itself to
12 establish some sort of abuse?

13 **A.** No, sir.

14 **Q.** Now, there's no need for a pharmacist to call a doctor
16:47:40 15 unless the pharmacist has a legitimate question about the
16 script. Is that correct?

17 **A.** Or suspects fraud.

18 **Q.** Okay. But other than that, a pharmacist is not
19 required to contact a doctor, correct?

16:47:53 20 **A.** Yes, sir.

21 **Q.** All right. Now, you testified about state laws in
22 response to Mr. Feran. Do you remember that?

23 **A.** Yes, sir.

24 **Q.** Isn't it a fact that in the state of Utah an online
16:48:12 25 pharmacy is permitted to operate without any in-person

Catizone - Cross (By Mr. Darken)

1 medical examination?

2 **A.** No, sir.

3 **Q.** Do you recall testifying at United States versus Jude
4 LaCour in Orlando, Florida, on April 14, 2009, and being
16:48:29 5 asked this question and giving the following answer:

6 "Q. When you stated that one of the online pharmacies
7 is certified by the state of Utah to operate without any
8 in-person medical exam, is that correct?

9 "A. Yes, sir."

16:48:46 10 Do you remember that?

11 **A.** Yes, sir.

12 **Q.** That's what you testified, right?

13 **A.** Yes, sir.

14 **Q.** In fact, the name of that company is called Quick Med;
16:48:53 15 is that right?

16 **A.** Yes, sir.

17 **Q.** And that's the same state that Dr. Nelson is from,
18 correct? Utah?

19 **A.** You asked me that earlier. I am not familiar with Dr.
16:49:06 20 Nelson, so I apologize, sir.

21 **Q.** All right. Now, isn't it a fact, sir, that a pharmacy
22 in Puerto Rico is permitted to use the Internet for a
23 prescription that is not based on a face-to-face
24 examination?

16:49:26 25 **A.** I'm not familiar with Puerto Rico. Sorry.

Catizone - Cross (By Mr. Darken)

1 **Q.** Okay. You testified at a case titled United States
2 versus Antonio Quinones in the Eastern District of New York
3 on or about October 29, 2008; correct?

4 **A.** Yes, sir.

16:49:42 5 **Q.** Do you recall this question and this answer?

6 "Q. Does the telemedicine law of Puerto Rico allow a
7 Puerto Rican doctor to use the Internet for a prescription
8 that is not based upon a face-to-face examination?

9 "A. Only in the Commonwealth of Puerto Rico."

16:50:07 10 Do you remember that

11 **A.** Now that you read it, yes, I do, sir.

12 **Q.** Now, in order for a pharmacist to have a valid
13 prescription there must be a bona fide relationship between
14 the patient and the prescriber. Is that correct, sir?

16:50:29 15 **A.** Yes, sir.

16 MR. DARKEN: One moment, Your Honor.

17 THE COURT: Sure.

18 **Q.** I'm going to show you what has been admitted as
19 Government's Exhibit 976. We're looking -- if I could have
16:51:37 20 a mic --

21 MS. LUTZKO: Your Honor.

22 **Q.** You've seen this before, right?

23 MS. LUTZKO: May I give him a copy?

24 (Handing.)

16:51:58 25 **A.** Thank you. Yes, I have seen it before.

Catizone - Cross (By Mr. Darken)

1 **Q.** Okay. And the part that says, for purposes of state
2 law, many state authorities consider the existence of the
3 following four elements as an indication that a legitimate
4 doctor-patient relationship has been established, and then
16:52:18 5 there's four elements, correct?

6 **A.** Yes, sir.

7 **Q.** Those are the four elements that you talked about,
8 right?

9 **A.** Yes, sir.

16:52:23 10 **Q.** Okay. But in this 2001 DEA guidance document it
11 doesn't say that the medical history has to be taken by the
12 prescribing practitioner, it just says that a medical
13 history has to be taken, correct?

14 **A.** Yes, sir.

16:52:40 15 **Q.** Similarly, in the 2001 guidance document it doesn't
16 say that the physical exam that has to be performed has to
17 be performed by the prescribing practitioner, correct?

18 **A.** It doesn't say that, but state law would require that.

19 **Q.** State law would require that. Okay. Well, you're
16:53:04 20 testifying here -- well, let me ask it this way. You
21 testified in response to Mr. Feran about state law, but you
22 never cited any specific state law, did you?

23 **A.** Florida.

24 **Q.** Florida. We'll talk about Florida in a minute.

16:53:25 25 **A.** Yes, sir.

Catizone - Cross (By Mr. Darken)

1 **Q.** Other than Florida, you haven't cited a single state
2 law, have you?

3 **A.** No, sir.

4 **Q.** All right. Well, let's take them. So Alabama, what
16:53:35 5 is the state law in Alabama that required a face-to-face
6 physical examination between October 2005 and February of
7 2009?

8 MR. FERAN: Objection, Your Honor.

9 THE COURT: Is Alabama involved in this?

16:53:54 10 MR. FERAN: It's one of the many prescriptions
11 were found in Alabama, Judge; whether he can cite Alabama
12 law is another question.

13 MR. DARKEN: May I respond?

14 THE COURT: You can ask him if he knows. If
16:54:05 15 he doesn't, there's nothing he can say.

16 **Q.** Do you know?

17 **A.** I don't know the specific citation, sir.

18 **Q.** Do you know there is an Alabama law between October
19 2005 and February 2009 that specifically requires
16:54:19 20 face-to-face examinations, sir?

21 **A.** Yes, I do.

22 **Q.** You do, but you don't know it?

23 **A.** I don't know the specific citation.

24 **Q.** Okay. You knew you were going to come to court today
16:54:30 25 with these three people on trial for their lives, right?

Catizone - Cross (By Mr. Darken)

1 **A.** Yes, sir.

2 **Q.** But you didn't think -- and you knew you were going to
3 be called as an expert on the laws of the entire United
4 States, right?

16:54:40 5 **A.** Yes, sir.

6 **Q.** But you didn't think that you should bring a list of
7 the laws that you were relying on? Is that correct?

8 **A.** I have the list and they're accessible, but I didn't
9 think I would need to present all of them, sir.

16:54:53 10 **Q.** Okay. Well, how about giving me any of them.

11 **A.** It's going to be the same response for every state
12 that you question me on, sir. I've reviewed the law in the
13 state, but I can't give you the specific citation.

14 **Q.** Well, the jury is just supposed to take your word for
16:55:09 15 it? Is that it?

16 **A.** As an expert witness, I think it's up to the jury to
17 decide whether my testimony is credible or not.

18 **Q.** Exactly.

19 THE COURT: Okay. No comments. It's got to
16:55:21 20 be a question. The previous one was a question, but that
21 last one was not.

22 MR. DARKEN: I apologize.

23 **Q.** Okay. Now, isn't it true, sir, that the state law of
24 Minnesota and the state law of New Jersey have the same four
16:55:42 25 components that we just looked at in the DEA guidance

Catizone - Cross (By Mr. Darken)

1 document? Isn't that true?

2 MR. FERAN: Objection, Your Honor.

3 THE COURT: Overruled. You can answer if you
4 remember the specifics.

16:55:56 5 **A.** I don't remember the specifics.

6 **Q.** Okay. Do you remember testifying at the trial of
7 United States versus Christopher Smith in the District of
8 Minnesota, Minneapolis, on November 15, 2006?

9 **A.** Yes, sir.

16:56:09 10 **Q.** Do you remember being asked this question and giving
11 the following answers? The following questions.

12 "Q. As part of your preparation and basis of knowledge for
13 this case, have you looked at certain state laws with regard
14 to physician-patient relationships?

16:56:25 15 "A. Yes.

16 "Q. And as an example, have you looked at Minnesota
17 law, New Jersey law?

18 "A. Yes.

19 "Q. And what do they say with regard to the
16:56:39 20 physician-patient relationship and valid prescriptions?

21 "A. Those states specifically require the four
22 components listed in the DEA directive for a valid
23 prescription to be in place. Legitimate medical need, a
24 physical, and the other two which I can't recall at this
16:56:56 25 time. And they also specifically say that questionnaires

Catizone - Cross (By Mr. Darken)

1 cannot be utilized solely as a basis for a valid
2 patient-physician relationship."

3 Do you remember that testimony?

4 **A.** Yes, sir.

16:57:06 5 **Q.** All right. So would you agree that Minnesota and New
6 Jersey at least as of 2006 had the same four components as
7 the DEA guidance document?

8 **A.** Yes, sir.

9 **Q.** All right. I've got a list of all 50 states here in
16:57:33 10 alphabetical order. If I ask you each state -- I don't want
11 to keep these people here, but if I ask you each state are
12 you going to give me the same answer? You don't remember
13 the specific state law that requires physical face-to-face
14 examination between October 2005 and February 2009?

16:57:50 15 **A.** I can identify Florida and the other states that I
16 prepared for this case, but the others I would not be able
17 to, sir.

18 **Q.** Okay. We're going to get to Florida. What other
19 states can you identify other than Florida?

16:58:01 20 **A.** Texas, Indiana, North Carolina, New York.

21 **Q.** And let's take Texas. What was the Texas law that
22 required face-to-face between October 2005 and February
23 2009?

24 **A.** Again, I can't give you the specific citation, but I
16:58:26 25 know that exists, sir.

Catizone - Cross (By Mr. Darken)

1 Q. Okay. How about North Carolina?

2 A. That's going to be the same answer for all those. I
3 don't have the specific citations memorized, sir.

4 Q. All right. Well, the Texas one, was it a statute?

16:58:41 5 Was it a regulation? Was it a Board of Pharmacy rule? Was
6 it a Board of Medicine rule? Or what was it?

7 A. The documents I reviewed were all regulations of the
8 Boards of Pharmacy.

9 Q. Pharmacy boards.

16:58:53 10 A. Yes, sir.

11 Q. And that's Texas, North Carolina, and what?

12 A. New York.

13 Q. New York. Did you say Indiana?

14 A. Indiana, Alabama.

16:59:03 15 Q. Alabama. Okay. All right. Let's talk about Florida.

16 THE COURT: Counsel, let me see counsel up
17 here for a minute.

18 (Proceedings at side-bar:)

19 THE COURT: I think we are running out of
16:59:40 20 time. You have some questions, about how much?

21 MR. DARKEN: An hour.

22 THE COURT: And what do you have.

23 MR. GORENCE: 10 or 15 minutes, Your Honor?

24 THE COURT: And what do you have?

16:59:55 25 MS. RHA: Right about an hour.

1 THE COURT: You have about an hour? We can't
2 do anything with that. We have to have him come back.

3 MR. DARKEN: That's fine.

4 THE COURT: Okay. Next Tuesday?

17:00:10 5 MS. LUTZKO: Your Honor, we have tomorrow
6 morning, right?

7 THE COURT: I'm sorry.

8 MR. DARKEN: We have half a day tomorrow.

9 THE COURT: I had a bad moment.

17:00:16 10 MS. LUTZKO: I will let you know right now
11 though that he does have obligations all week next week and
12 the following week.

13 MR. DARKEN: We can finish him tomorrow.

14 THE COURT: I was just asleep at the switch
17:00:27 15 there. That should be enough.

16 MS. LUTZKO: I would hope so.

17 THE COURT: All right.

18 MR. DARKEN: What time do you want to start
19 tomorrow?

17:00:34 20 THE COURT: Be ready at 8:30.

21 (Proceedings had in open court:)

22 THE COURT: Okay. We're at 5:00, so 8:30
23 tomorrow. And then you'll be ready to stay until 12:30, and
24 then you can go. All right? Have a good evening.

17:01:11 25 A JUROR: Good night.

1 THE COURT: And don't talk about the case.

2 (Proceedings had out of the presence of the
3 Jury:)

4 MR. GORENCE: Your Honor, with this long
17:01:47 5 weekend, Ms. Rovedo is going to return to Florida. She has
6 been in contact with her Probation officer or Pretrial
7 Services officer, I should say, and they just got an e-mail
8 today saying she couldn't leave until she had the Court's
9 permission. So she has her tickets, and she'll be back, of
17:02:07 10 course, but I just want to get verbal permission because I
11 think I don't have time to file another motion.

12 THE COURT: To my knowledge, to my knowledge
13 there have been no issues raised with me by Pretrial and
14 Probation in regard to her, so I would not have any
17:02:26 15 difficulty with her going home and coming back with
16 everybody else.

17 MS. LUTZKO: We don't object.

18 MR. GORENCE: That's all. And I'll
19 communicate that to the Pretrial Services officer, but there
17:02:36 20 seemed to be some snafu. She was waiting for guidance from
21 you, and I'll communicate that. Thank you, Your Honor.

22 THE COURT: All right.

23 - - - - -

24 (Proceedings adjourned.)

25

Catizone - Cross (By Mr. Darken)

1 MORNING SESSION, THURSDAY, OCTOBER 11, 2012 8:40 A.M.

2 (Proceedings in the presence of the Jury:)

3 THE COURT: Good morning. What a beautiful
4 day for an afternoon off.

08:40:24 5 A JUROR: Yes, it is.

6 THE COURT: All right come forward, sir: Good
7 morning.

8 THE WITNESS: Good morning, sir.

9 THE COURT: You understand you're still under
08:40:47 10 oath.

11 THE WITNESS: Yes, sir.

12 THE COURT: All right.

13 CROSS-EXAMINATION OF CARMEN CATIZONE (RESUMED)

14 BY MR. DARKEN:

08:40:51 15 **Q.** Good morning, Mr. Catizone.

16 **A.** Good morning, sir.

17 **Q.** Sir, I want to start off by asking you some questions
18 about the NABP website. That's the website for your
19 organization, correct?

08:41:02 20 **A.** Yes, sir.

21 **Q.** On the website there's different sections of the
22 website you can look at, correct?

23 **A.** Yes, sir.

24 **Q.** And there's a section called resolutions, correct?

08:41:16 25 **A.** Yes, sir.

Catizone - Cross (By Mr. Darken)

1 Q. What is a resolution?

2 A. A resolution is a direction goal that is set by the
3 individual states for NABP.

4 Q. And on the website there seemed to be an indication
08:41:32 5 that some resolutions had passed and some had not passed.
6 How does a resolution pass?

7 A. Each state has one vote, and a majority of states
8 voting for resolution would indicate pass.

9 Q. And on the website there's an archive of resolutions
08:41:51 10 that goes way back, correct?

11 A. Yes, sir.

12 Q. And those resolutions are kept on the website as part
13 of the ordinary course of the business of your organization,
14 correct?

08:42:02 15 A. Yes, sir.

16 Q. Resolutions are passed as part of the ordinary course
17 of your business, correct?

18 A. Yes, sir.

19 Q. Okay. I'm going to show you what's been marked for
08:42:12 20 identification as VD Number 5. VD Number 5 is a resolution
21 from your organization from May 22, 2007, correct?

22 A. Yes, sir.

23 Q. And the title is Valid Ongoing Patient Prescriber
24 Relationship, Resolution Number 103-2-07. Correct?

08:42:54 25 A. Yes, sir.

Catizone - Cross (By Mr. Darken)

1 **Q.** And that indicates that the resolution is that NABP
2 work with the Federation of State Medical Boards, U.S. Food
3 and Drug Administration, U.S. Drug Enforcement
4 Administration, and other interested stakeholders to assess
08:43:13 5 and revise, if necessary, the model State Pharmacy Act and
6 the model rules of the National Association of Boards of
7 Pharmacy to explicitly prohibit the dispensing of
8 medications based on prescriptions generated solely from
9 Internet-based, electronic questionnaires, or cyberspace
08:43:34 10 consultations, or invalid patient-prescriber relationships.
11 Correct?

12 **A.** Yes, sir.

13 MR. DARKEN: Your Honor, I move for the
14 admission of VD-5.

08:43:58 15 THE COURT: I'm sorry?

16 MR. DARKEN: I move for the admission of VD-5.

17 THE COURT: Any objection?

18 MR. FERAN: No objection, Judge.

19 THE COURT: Okay.

08:44:08 20 **Q.** Now, sir, this is the first resolution from your
21 organization addressing patient-prescriber relationships in
22 the connection with Internet-based websites, correct?

23 **A.** Possibly, yes. Possibly.

24 **Q.** Okay. Well, put it this way: You're not aware of any
08:44:40 25 resolution prior to this May 22, 2007 that addressed this

Catizone - Cross (By Mr. Darken)

1 subject, correct?

2 **A.** I'm aware of recommendations that function the same as
3 resolutions from the task force that we had in 1999 that
4 addressed the situation, sir.

08:44:55 5 **Q.** Did you hear my question, sir?

6 **A.** I did.

7 **Q.** You didn't answer it, did you?

8 **A.** I did, sir.

9 **Q.** Okay. Let me ask it again: Isn't it a fact, sir,
08:45:05 10 that prior to this May 22, 2007 resolution, you're not aware
11 of any other resolution passed by your organization that
12 addressed patient-prescriber relationships for Internet
13 websites. Isn't that a fact?

14 **A.** Yes, sir, I'm not aware.

08:45:28 15 **Q.** Thank you. Now, you testified before the Federal
16 Trade Commission Internet Workshop on Telemedicine and
17 Pharmaceutical Panels, and you had a prepared statement.
18 Correct?

19 **A.** Yes, sir.

08:45:47 20 **Q.** Isn't it a fact that in that statement you stated,
21 quote, only five states have enacted additional regulations
22 for Internet pharmacies?

23 **A.** Yes, sir.

24 **Q.** When was that statement made?

08:45:59 25 **A.** I don't recall the exact date, sir.

Catizone - Cross (By Mr. Darken)

1 Q. What is your best guess?

2 A. 2007.

3 Q. Now, on your website, in addition to the resolution
4 section you also have a news section, correct?

08:46:19 5 A. Yes, sir.

6 Q. And in the news section of the website you or your
7 organization re-publishes sometimes sections of state Board
8 of Pharmacy newsletters, correct?

9 A. Yes, sir.

08:46:33 10 Q. And you also sometimes republish sections of your own
11 NABP newsletter, correct?

12 A. Yes, sir.

13 Q. And you do that as part of the ordinary course of your
14 organization's business, correct?

08:46:46 15 A. Yes, sir.

16 Q. And you keep those things on the website as part of
17 the ordinary course of business so your members can see
18 them, correct?

19 A. Correct.

08:46:54 20 Q. Okay. I'm going to hand you what's been marked for
21 identification as VD-3.

22 MR. DARKEN: One moment, Your Honor.

23 Q. What I've handed you marked for identification as VD-3
24 is one of those news items from October of 2008, correct?

08:47:44 25 A. Yes, sir.

Catizone - Cross (By Mr. Darken)

1 Q. And it's a reprint from the October 2008 Minnesota
2 Board of Pharmacy Newsletter. Is that correct?

3 A. Yes, it is, sir.

4 Q. Okay. And that indicates in the second paragraph that
08:47:57 5 the Minnesota legislature passed a law earlier this year,
6 earlier 2008, that establishes that prescriptions for
7 controlled substances and certain other drugs are not valid
8 unless the prescriptions or orders are based on a documented
9 patient evaluation, including an inpatient examination,
08:48:19 10 adequate to establish a diagnosis and identify underlying
11 conditions and contraindications to treatment. Correct?

12 A. Yes, sir.

13 MR. DARKEN: Your Honor, I move for the
14 admission of VD-3.

08:48:33 15 MR. FERAN: No objection.

16 THE COURT: It shall be admitted.

17 Q. You're familiar with -- let me put it this way. Your
18 organization reported on your website about the Ryan Haight
19 Act, correct?

08:49:01 20 A. Yes, sir.

21 Q. And you're familiar with William Winsley, the
22 executive director of the Ohio Board of Pharmacy; correct?

23 A. Yes, sir.

24 Q. Are you aware that William Winsley testified before
08:49:16 25 Congress on June 24, 2008 --

Catizone - Cross (By Mr. Darken)

1 MR. FERAN: Objection, Your Honor.

2 THE COURT: He has an objection going.

3 MR. DARKEN: I can rephrase it, Your Honor.

4 THE COURT: All right.

08:49:30 5 Q. You've given us your opinion, expert opinion, correct?

6 A. Yes, sir.

7 Q. Would it affect your expert opinion to know that on
8 June 24, 2008, William Winsley, executive director of the
9 Ohio Board of Pharmacy, provided written testimony to a
08:49:46 10 Congressional committee in a hearing on online pharmacies,
11 and stated that state laws and rules relating to Internet
12 pharmacies vary widely. Would that affect your opinion?

13 A. No, sir.

14 Q. Now, you've said that your organization publishes a
08:50:09 15 newsletter, correct?

16 A. Yes, sir.

17 Q. Did you read the February 2009, February 2009 article,
18 Federal/State Governments Pass Legislation to Address Rogue
19 Internet Drug Outlets?

08:50:30 20 A. Yes, sir.

21 Q. Isn't it a fact, sir, that that article states that
22 New Hampshire --

23 MR. FERAN: Objection, Your Honor.

24 Q. -- passed --

08:50:42 25 THE COURT: This is from his -- this is

Catizone - Cross (By Mr. Darken)

1 from --

2 MR. DARKEN: It is from his organization's
3 newsletter.

4 THE COURT: Do you have a problem with
08:50:52 5 presenting him with something from his own newsletter?

6 MR. FERAN: The time period, Your Honor. It
7 is outside the time period.

8 THE COURT: What was the time frame?

9 MR. DARKEN: June of 2008, Your Honor. It's
08:51:02 10 during the conspiracy, alleged conspiracy.

11 MR. FERAN: You said February '09.

12 MR. DARKEN: The article is February '09, what
13 it's reporting about is June of '08.

14 THE COURT: It's talking about June of '08?

08:51:13 15 MR. DARKEN: Yes.

16 THE COURT: Okay. As long as whatever you
17 were talking about was before means it was in the time of
18 the conspiracy.

19 MR. DARKEN: Yes.

08:51:21 20 THE COURT: Okay.

21 BY MR. DARKEN:

22 **Q.** Isn't it a fact, sir, that in that article it states
23 that New Hampshire passed a statute -- I'll just quote
24 it -- does it say "New Hampshire joined the ranks of those
08:51:39 25 states spelling out elements of a legal patient-practitioner

Catizone - Cross (By Mr. Darken)

1 relationship in June of 2008 when the state's governor
2 signed into law a bill that specified the need for such
3 relationship in the issuance of a prescription"?

4 **A.** Yes, sir.

08:51:56 5 **Q.** And didn't that article further state, quote,
6 "Minnesota's legislature, too, passed a law in 2008
7 requiring that prescriptions for controlled substances and
8 certain other drugs be based on a documented patient
9 evaluation, including an in-person examination." Isn't that
08:52:14 10 true?

11 **A.** Yes, sir.

12 **Q.** Isn't it true that the same article says, quote,
13 "Other states that considered similar legislation in 2008
14 included Illinois and Massachusetts."

08:52:25 15 **A.** Yes, sir.

16 **Q.** When a state is considering legislation, that means
17 the state hasn't passed it yet, correct?

18 **A.** Correct, sir.

19 **Q.** Okay. Now, you stated in response to Mr. Feran that
08:52:45 20 your organization has this database where you have all the
21 pharmacy laws for every state online somehow, correct?

22 **A.** Yes, sir.

23 **Q.** All right. And you follow those laws as they change,
24 correct?

08:53:01 25 **A.** Yes, sir.

Catizone - Cross (By Mr. Darken)

1 **Q.** I will show you what's marked for identification as
2 Darji 7 H's. That document is an act to amend the Arkansas
3 Internet Prescription Consumer Protection Act, and it was
4 enacted, approved February 21, 2007; correct?

08:53:50 5 **A.** Yes, sir.

6 **Q.** Okay.

7 MR. DARKEN: Move for the admission of Darji
8 HHHHHHH, Your Honor.

9 MR. FERAN: No objection, Judge.

08:54:00 10 THE COURT: It shall be admitted.

11 **Q.** I will show you what's marked for identification as
12 Darji GGGGGGG. Sir, that exhibit is a Louisiana statute
13 passed sometime in 2007 which imposed the requirement that a
14 prescription issued solely upon the results of answers to an
08:54:45 15 electronic questionnaire in the absence of a documented
16 patient evaluation including a physical examination shall be
17 considered issued outside the context of a valid
18 physician-patient relationship and shall not be a valid
19 prescription. Correct?

08:54:59 20 **A.** Yes, sir.

21 **Q.** And that was passed in 2007, correct?

22 **A.** Yes, sir.

23 MR. DARKEN: Move for the admission of Darji
24 Exhibit GGGGGGG, Your Honor.

08:55:07 25 MR. FERAN: No objection.

Catizone - Cross (By Mr. Darken)

1 THE COURT: It shall be admitted.

2 Q. Showing you what's marked for identification as Darji
3 FFFFFFFF. That exhibit is the statute from the state of
4 Hawaii, correct?

08:55:43 5 A. Yes, sir.

6 Q. And that was effective April 28, 2009; is that
7 correct?

8 A. Yes, sir.

9 Q. And that states in part, "Treatment recommendations
08:55:55 10 made by telemedicine, including issuing a prescription via
11 electronic means, shall be held to the same standards of
12 appropriate practice as those in traditional
13 physician-patient settings that do not include a
14 face-to-face visit," correct?

08:56:09 15 A. Yes, sir.

16 Q. Okay. And then it further states that "Issuing a
17 prescription based solely on an online questionnaire is not
18 treatment for the purposes of this section and does not
19 constitute an acceptable standard of care." Correct?

08:56:25 20 A. Yes, sir.

21 Q. And this was passed -- or it's effective April 28,
22 2009.

23 A. Yes, sir.

24 Q. Okay. Now, you've testified -- we'll switch topics.
08:56:41 25 You've testified that you did a lot of media work, correct?

Catizone - Cross (By Mr. Darken)

1 **A.** Yes, sir.

2 **Q.** And you went on the Oprah show?

3 **A.** Yes, sir.

4 **Q.** All right. Do you remember telling a reporter for

08:56:59 5 CNET news, quote, "In the early years of the Internet it was

6 a case of entrepreneurs not understanding the legal

7 requirements for the dispensing of drugs."

8 **A.** Yes, sir.

9 **Q.** Now, as part of your job you followed federal

08:57:26 10 legislation, correct?

11 **A.** Yes, sir.

12 **Q.** All right. Do you recall reviewing a Congressional

13 research service report done for Congress titled Legal

14 Issues Related to Prescription Drug Sales on the Internet?

08:57:43 15 Do you remember seeing that in May of 2005?

16 **A.** Yes, sir.

17 **Q.** That indicated that, quote, "While some states specify

18 whether or not prescriptions based on online questionnaires

19 are valid, other state laws fail to address the issue."

08:57:59 20 Correct?

21 **A.** Yes, sir.

22 **Q.** Are you familiar with a 2004 American Health Lawyers

23 Association article concerning Internet pharmacies?

24 **A.** Not that I specifically recall, sir.

08:58:21 25 **Q.** Would you agree with the statement that as of 2004

Catizone - Cross (By Mr. Darken)

1 most states have not passed laws regulating Internet
2 pharmacies?

3 **A.** Yes.

4 **Q.** Now, you testified in response to Mr. Feran that one
08:58:48 5 of the ways states can determine a valid physician-patient
6 relationship is through case law. Do you remember saying
7 that?

8 **A.** No, sir, I said it was one of the tenets that are used
9 to provide the requirement for physical examination, not to
08:59:10 10 determine.

11 **Q.** Are you familiar with a case called McKinney versus
12 Schlatter or "Schlatter" in the Ohio Court of Appeals from
13 1997?

14 **A.** No, sir.

08:59:21 15 **Q.** Are you aware of cases in any state establishing that
16 a physician-patient relationship can start without a
17 face-to-face interaction?

18 **A.** No, sir.

19 **Q.** Would it affect your opinion if you knew that courts
08:59:43 20 in Ohio, the Kansas Supreme Court, and New York State
21 Supreme Court, and the Missouri Supreme Court, and the Texas
22 Supreme Court have held that in certain circumstances a
23 physician-patient relationship can begin without
24 face-to-face interaction? Would that affect your opinion,
09:00:07 25 or no?

Catizone - Cross (By Mr. Darken)

1 **A.** If I had a chance to review the entire case it might,
2 but I can't say, sir.

3 **Q.** Okay. Well, I don't have the whole case, but let me
4 show you this footnote.

09:00:30 5 MR. FERAN: Judge, I object to this.

6 THE COURT: Okay. You say it's just a
7 footnote?

8 MR. FERAN: I want him to read the whole case.

9 MR. DARKEN: All I have is the footnote.

09:00:39 10 MR. FERAN: I object, Judge.

11 THE COURT: Sustained.

12 **Q.** You know Benjamin Gluck, right?

13 **A.** I'm not -- I don't think so.

14 **Q.** Okay. There is a May 2008 conference sponsored by
09:01:11 15 your organization, and he's a lawyer from a firm called
16 Bird, Marella, and he spoke at that. Did you attend that
17 conference?

18 **A.** I probably did, sir.

19 **Q.** All right. Do you recall Mr. Gluck stating at that
09:01:39 20 conference in May 2008 before your organization, "29 states,
21 58 percent, have medical board policies addressing online
22 prescribing. Some only say things like use of Internet does
23 not change standards of care, citing New York. Most merely
24 deem it unprofessional. None of these say it is outside the
09:02:07 25 course or an invalid prescription." Do you remember that?

Catizone - Cross (By Mr. Darken)

1 **A.** I don't remember it, but I'm sure it occurred.

2 **Q.** All right. Do you remember Mr. Gluck at that
3 conference further stating that 15 states, 30 percent, have
4 statutes addressing online prescribing. Some merely address
09:02:27 5 cross-border licensing issues. Most merely deem it
6 unprofessional, only Nevada and Virginia prohibit it." Do
7 you recall that?

8 **A.** I don't recall, but I'm sure that he made those
9 statements at our conference.

09:02:41 10 **Q.** Okay. Do you recall Mr. Gluck putting together this
11 map entitled Internet Prescribing as a Medical Practice, and
12 the only two states that are blacked out are Nevada and
13 Virginia?

14 **A.** Same response. I don't remember it, but I'm sure he
09:02:55 15 presented it.

16 **Q.** Do you remember Mr. Gluck talking about the climate
17 summary and stating, quote, "The medical community does not
18 reflect the consensus that DEA purports to rely on. The
19 legal community similarly does not reflect the purported
09:03:14 20 consensus." Do you remember that?

21 **A.** Same response, sir.

22 **Q.** Mr. Gluck was a speaker at your organization, was
23 brought in to talk at that conference, wasn't he?

24 **A.** Yes, sir.

09:03:41 25 **Q.** We're going to shift topics. You were shown by

Catizone - Cross (By Mr. Darken)

1 Mr. Feran the Model Guidelines for the Appropriate Use of
2 the Internet in Medical Practice put out by the Federation
3 of State Medical Boards in 2002, and you read part of that,
4 correct?

09:03:56 5 **A.** Yes, sir.

6 MR. DARKEN: Your Honor, at this time we move
7 for the admission of that document. My copy is marked Darji
8 Defendant Exhibit C.

9 THE COURT: Any objection?

09:04:04 10 MR. FERAN: No, Judge. We'd like a Joint
11 Exhibit, or however he wants to admit it, we want it
12 admitted, too.

13 MR. DARKEN: That's fine. We can mark it with
14 the government number, Your Honor, that's fine.

09:04:15 15 MR. FERAN: Thank you.

16 **Q.** Do you remember Mr. Feran asked you about the purpose,
17 what did you think the purpose of this was, and you gave
18 your answer? Do you remember that?

19 **A.** Yes, sir.

09:04:34 20 **Q.** All right. Now, the other side of the website are
21 customers, correct?

22 **A.** The federation's website, sir?

23 **Q.** No. I'm sorry, poor question. When we're looking at
24 the USMeds website we've got the website, the doctors, the
09:05:02 25 pharmacies, but the other side are the customers or

Catizone - Cross (By Mr. Darken)

1 patients, correct?

2 **A.** Yes, sir.

3 **Q.** All right. And they have to want to buy or pay for
4 these orders in order for this website to function, correct?

09:05:21 5 **A.** I believe so, sir, yes.

6 **Q.** All right. You were interviewed in December 2003 by
7 the *Fort Worth Star Telegram*. Do you recall saying, quote,
8 "The health care system is inaccessible, Catizone said. You
9 wait three weeks to see a doctor for 10 seconds, then you
09:05:43 10 wait 45 minutes for prescriptions." Do you remember saying
11 that?

12 **A.** Yes, sir.

13 **Q.** Now we'll move on. You were asked about electronic
14 signatures, and you testified that your opinion was that
09:06:09 15 only faxes were valid, but not Internet prescriptions.
16 Correct?

17 **A.** No, sir, I testified that oral and fax prescriptions
18 at that time period were only allowed, and Internet
19 transmission of prescriptions was not allowed.

09:06:25 20 **Q.** I'm sorry. Thank you. Okay. I want to show you
21 what's marked for identification as VD-4. Now, that's one
22 of those news items that was posted on your organization's
23 website in the news section, correct?

24 **A.** Yes, sir.

09:07:08 25 **Q.** That's a reprint from the July 2006 North Carolina

Catizone - Cross (By Mr. Darken)

1 Board of Pharmacy newsletter, correct?

2 **A.** Yes, sir.

3 **Q.** All right. Now, let me ask you this: Isn't it true
4 that at some point the Medicare Part D program was directed
09:07:28 5 to develop uniform standards for e-prescribing?

6 **A.** Yes, sir.

7 **Q.** And the purpose of that was for potential cost savings
8 and patient safety improvement. Is that correct?

9 **A.** Yes, sir.

09:07:42 10 **Q.** It's just that that had not come into effect at the
11 time you were talking about, correct?

12 **A.** It just came into effect this year, sir.

13 **Q.** I'm going to show you what's marked for identification
14 as VD-8. That's a letter dated August 24, 2011 to you from
09:08:29 15 Joseph Renzi, Deputy Administrator, Office of Diversion
16 Control, Drug Enforcement Administration, correct?

17 **A.** Yes, sir.

18 **Q.** And that's a response to a letter that you wrote dated
19 July 26, 2011, correct?

09:08:42 20 **A.** Yes, sir.

21 **Q.** And you wrote that in your capacity as executive
22 director of your organization, correct?

23 **A.** Yes, sir.

24 **Q.** And you were seeking clarification on DEA's policy
09:08:56 25 when a pharmacist has information missing from a Schedule II

Catizone - Cross (By Mr. Darken)

1 script, correct?

2 **A.** Yes, sir.

3 **Q.** All right. And specifically, the question was, if a
4 practitioner's DEA number is missing or if the patient's
09:09:15 5 name or address is wrong, what is the pharmacist to do,
6 correct?

7 **A.** Yes, sir.

8 **Q.** And you wanted advice from DEA, correct?

9 **A.** Yes, sir.

09:09:24 10 **Q.** All right. And you were told, were you not, that
11 whether it is appropriate for a pharmacist to make changes
12 to the prescription, such as adding a practitioner's DEA
13 number or correcting a patient's name or address, varies
14 case by case. Correct?

09:09:41 15 **A.** Yes, sir.

16 **Q.** All right. And you were told that when information is
17 missing or needs to be changed on a Schedule II controlled
18 substance prescription pharmacists use their professional
19 judgment, correct?

09:09:56 20 **A.** Yes, sir.

21 **Q.** Okay. Now, Schedule II, as everybody knows, is more
22 controlled than Schedule III, like hydrocodone, correct?

23 **A.** Yes, sir.

24 **Q.** All right. So here the situation was the pharmacist
09:10:15 25 gets a script for a Schedule II that doesn't even have a DEA

Catizone - Cross (By Mr. Darken)

1 number on it, correct?

2 **A.** Yes, sir.

3 **Q.** All right. And the pharmacist, according to this
4 letter, is allowed to deal with that using his or her best
09:10:30 5 professional judgment, correct?

6 **A.** No, sir.

7 **Q.** Okay. Well, doesn't that document say whether it is
8 appropriate for a pharmacist to make changes to the
9 prescription, such as adding the practitioner's DEA number
09:10:51 10 to the prescription, or correcting the patient's name or
11 address, varies case by case based on the facts present,
12 that should be presented? Right? The facts present. I'm
13 sorry. That's what it says, right?

14 **A.** Yes, sir. The second part said knowledge of state and
09:11:11 15 federal laws. That's a very important part of that
16 sentence, sir. It says professional judgment and knowledge
17 of state and federal laws.

18 **Q.** Okay. The next sentence states, "Consequently, DEA
19 expects that when information is missing or needs to be
09:11:24 20 changed on a Schedule II controlled substance prescription
21 pharmacists use their professional judgment and knowledge of
22 state and federal laws and policies to decide whether it is
23 appropriate to make changes to the prescription." Is that
24 correct?

09:11:36 25 **A.** Yes, sir.

Catizone - Cross (By Mr. Darken)

1 Q. Well, if it was so obvious under state or federal law,
2 why did you have to write that letter to DEA and ask them?

3 A. The DEA had issued a prior letter saying that
4 pharmacists could not add the DEA number or add the
09:11:52 5 patient's name, or any other information.

6 Q. Okay. So DEA sent the prior letter, and then you
7 wrote a letter asking them to reconsider, or challenging
8 them, or what?

9 A. Asking them to reconsider, sir.

09:12:14 10 Q. You didn't think it was entirely clear or you wouldn't
11 have written the letter, right?

12 A. Correct.

13 MR. DARKEN: One moment, Your Honor.

14 Q. Now we're going to go quickly through some statements
09:12:46 15 you made on direct.

16 Do you remember testifying in response to Mr. Feran
17 about the number of controlled substances versus
18 noncontrolled substances regarding Mr. Darji?

19 A. Yes, sir.

09:13:13 20 Q. And you testified that your opinion was this was done
21 to disguise the ordering pattern, correct?

22 A. Yes, sir.

23 Q. Now, we've heard testimony from a DEA official about
24 the ARCOS data. You're familiar with ARCOS data, correct?

09:13:33 25 A. Yes, sir.

Catizone - Cross (By Mr. Darken)

1 **Q.** Now, if I'm a pharmacist and I order a hundred
2 controls and a hundred noncontrols, DEA sees that I ordered
3 a hundred controls, correct?

4 **A.** Yes, sir.

09:13:46 5 **Q.** There's no way for me to hide the fact that I ordered
6 a hundred controls; whether I order zero controls or a
7 hundred controls, DEA still knows I ordered a hundred
8 controls, right?

9 **A.** Yes, sir.

09:14:05 10 **Q.** Now, you testified in response to Mr. Feran about
11 dispensing fees. Do you remember that?

12 **A.** Yes, sir.

13 **Q.** And you said that for a pharmacist operating -- for
14 patients with insurance plans they get paid somewhere
09:14:16 15 between 50 cents and \$2.50 per script. Is that correct?

16 **A.** Yes, sir.

17 **Q.** All right. But isn't it true that a lot of people in
18 this country are not insured?

19 **A.** No, sir.

09:14:30 20 **Q.** It's not true?

21 **A.** No. Presently 97 percent of the prescriptions that
22 are dispensed by pharmacies are filled under insurance
23 plans.

24 **Q.** Well, let me put it this way: There's no law in this
09:14:46 25 country that sets a price that a pharmacist -- the fill fee

Catizone - Cross (By Mr. Darken)

1 a pharmacist can charge for a cash transaction. Isn't that
2 true?

3 **A.** Correct, sir.

4 **Q.** All right. Now, you're familiar in medical insurance
09:15:08 5 that certain procedures are not covered by insurance,
6 correct? They're cash only procedures?

7 **A.** As a layperson, but not as an expert, sir.

8 **Q.** Right. I understand that. But for example, certain
9 types of cosmetic procedures are not covered by insurance.
09:15:23 10 You have to pay cash to have them done, right?

11 **A.** Again, from what I know as a patient, not as a
12 pharmacist or expert, sir.

13 **Q.** And when the doctor does those procedures, the doctor
14 says, well, I'll do this cosmetic procedure if you pay me X.
09:15:37 15 Correct?

16 **A.** I believe so.

17 **Q.** All right. And that's legal, right?

18 **A.** Again, as a person and a patient, I would say yes.

19 **Q.** All right. Now, you were asked a number of questions,
09:15:54 20 do you remember Mr. Feran went through Laura Keeley and all
21 of her prescriptions? Do you remember that?

22 **A.** Yes, sir.

23 **Q.** I'm not going to bring them all up here, but the dates
24 were May 1 '06, May 30 '06, July 5 '06, August 4 '06,
09:16:17 25 November 8 '06. They're all about 30 days apart, right?

Catizone - Cross (By Mr. Darken)

1 **A.** Yes, sir.

2 **Q.** All right. So she wasn't filling early, correct?

3 **A.** Yes, sir.

4 **Q.** Now, you testified about Laura Keeley, and Nikisha

09:16:34 5 Dawson, or -- I think that's right, and they had the same

6 address on their scripts. Correct?

7 **A.** Yes, sir.

8 **Q.** All right. Now, you worked at Osco Drugs; is that

9 right?

09:16:45 10 **A.** I used to, sir.

11 **Q.** When did you work at Osco Drugs?

12 **A.** From 1978 to 1985.

13 **Q.** Okay. And when you worked at Osco Drugs, that's a

14 chain, right?

09:16:57 15 **A.** Yes, sir.

16 **Q.** All right. Did you have pharmacy techs who worked

17 under you?

18 **A.** Yes, sir.

19 **Q.** Now, I know you testified that the pharmacist in

09:17:09 20 charge is ultimately in charge, correct?

21 **A.** Yes, sir.

22 **Q.** All right. You don't really expect Mr. Darji to

23 physically compare every prescription against every other

24 prescription to match up addresses, do you?

09:17:25 25 **A.** Yes.

Catizone - Cross (By Mr. Darken)

1 **Q.** Okay. You expect him personally to do that or his
2 techs to do that?

3 **A.** Mr. Darji would establish a system that he would be
4 responsible for to make sure that occurred.

09:17:42 5 **Q.** Right. And in your view he's responsible for setting
6 up the system, but he's not responsible for personally
7 crosschecking every prescription against every other
8 prescription to match up addresses. Is that right?

9 **A.** Under law he is personally responsible if that system
09:17:57 10 fails.

11 **Q.** Now, when you testified "under law," okay, do you
12 understand the difference between pharmacy board law in a
13 state and criminal law? You understand that difference?

14 **A.** Yes, sir.

09:18:12 15 **Q.** Okay. And that's a big difference; isn't that true?

16 **A.** Yes, sir.

17 **Q.** Okay. Now, you talked in response to Mr. Feran about
18 Mr. Darji spreading prescriptions among three pharmacies.
19 Do you remember that?

09:18:30 20 **A.** Yes, sir.

21 **Q.** What evidence do you have that Mr. Darji -- well, back
22 up. One of Mr. Darji's prescriptions was -- one of
23 Mr. Darji's pharmacies was primarily for ALF homes. Are you
24 aware of that?

09:18:47 25 **A.** Yes, sir.

Catizone - Cross (By Mr. Darken)

1 **Q.** What evidence do you have that he spread hydrocodone
2 prescriptions into that pharmacy?

3 **A.** The taped conversations, the wiretaps that I read in
4 the report, talked about spreading the prescriptions around
09:19:05 5 and utilizing certain doctors because the DEA and others
6 were becoming aware of that, and how to hide those
7 prescription totals, and what they could do to conceal that
8 activity. That's where I came up with my opinion, sir.

9 **Q.** Okay. Now, this jury has heard one phone call between
09:19:22 10 Mr. Hazelwood and Mr. Darji. Is that what you're relying
11 on?

12 **A.** There were several calls that they taped of
13 Mr. Hazelwood between Mr. Hazelwood, Miss Rovedo, and some
14 of the others involved where they talked about the
09:19:35 15 operation, sir.

16 **Q.** Okay. I'm focused on Mr. Darji, just Mr. Darji. Do
17 you understand?

18 **A.** Yes, sir.

19 **Q.** Okay. Now, you didn't hear -- well, did you actually
09:19:46 20 listen to the April 29 call between Mr. Darji and
21 Mr. Hazelwood, or not?

22 **A.** No, sir.

23 **Q.** No. Okay. So you don't really know, right?

24 **A.** Just what I read in the reports, sir.

09:19:58 25 **Q.** Okay. Well, you're not aware of any other call

Catizone - Cross (By Mr. Darken)

1 between Mr. Hazelwood and Mr. Darji other than the April 29
2 call, are you?

3 **A.** No, sir.

4 **Q.** Okay.

09:20:21 5 MR. DARKEN: One moment, Your Honor.

6 **Q.** Now, we said yesterday, we talked about Florida law.
7 Do you remember that?

8 **A.** Yes, sir.

9 **Q.** Let me show you what's marked -- I'll bring them up at
09:20:44 10 the same time -- marked for identification as VD-7 and Darji
11 EEEEEEEE. (Hanging.)

12 **A.** Thank you.

13 **Q.** Now, Mr. Feran asked you some questions about VD-7,
14 which is Florida Administrative Code 64 B 16-27.831.

09:21:40 15 Correct?

16 **A.** Yes, sir.

17 **Q.** And you read a section that stated that one of the
18 criteria which would cause a physician to question whether a
19 prescription was issued for a legitimate medical purpose was
09:21:58 20 only controlled substance prescriptions are prescribed for a
21 patient. Is that correct?

22 **A.** It's for the pharmacist, sir, not for the physician.
23 This is within the borders --

24 **Q.** You're right, I'm sorry. And that's the section that
09:22:09 25 you read, correct?

Catizone - Cross (By Mr. Darken)

1 **A.** Yes, sir.

2 **Q.** And that's one of five criteria, correct?

3 **A.** Yes, sir.

4 **Q.** All right. And this was the Florida Administrative

09:22:28 5 Code section which was in effect at least as of 2003,

6 correct?

7 **A.** Yes, sir.

8 **Q.** All right. Now, isn't it true that other factors

9 which pharmacists should consider in terms of whether or not

09:22:49 10 a prescription was issued for a legitimate medical purpose

11 was, A, frequent loss of controlled substance medications,

12 correct?

13 **A.** Yes, sir.

14 **Q.** You don't have any evidence that in this case

09:23:02 15 Mr. Darji was informed that any of these patients had

16 frequent loss of controlled substance medications, correct?

17 **A.** Correct.

18 **Q.** And then B you talked about with Mr. Feran. C, one

19 person presents controlled substance prescriptions with

09:23:21 20 different patient names. Correct?

21 **A.** Yes, sir.

22 **Q.** That's a version of double dipping, right?

23 **A.** Yes, sir.

24 **Q.** Are you aware that Mr. Darji's techs worked to weed

09:23:36 25 out double dippers?

Catizone - Cross (By Mr. Darken)

1 **A.** No.

2 **Q.** You are not aware of that?

3 **A.** No, sir.

4 **Q.** The government didn't tell you that?

09:23:42 5 **A.** No, sir.

6 **Q.** Have you seen any documents from the government
7 showing that Mr. Darji did that?

8 **A.** No, sir.

9 **Q.** Okay. Then the next factor, same or similar
09:23:57 10 controlled substance medication is prescribed by two or more
11 prescribers at the same time. Correct?

12 **A.** Yes, sir.

13 **Q.** That's another version of double dipping, that's
14 doctor shopping, where I'm a patient and I go to doctor A
09:24:08 15 and get a script, and then I go to doctor B and get a
16 script. Correct?

17 **A.** One of the double dipping ways, yes, sir.

18 **Q.** And the same thing: You're not aware that Mr. Darji's
19 techs tried to weed out those double dippers, are you?

09:24:24 20 **A.** No, sir.

21 **Q.** And you haven't seen any documents from the government
22 showing you that, right?

23 **A.** No, sir.

24 **Q.** All right. E, patient always pays cash and always
09:24:32 25 insists on brand name product. Correct?

Catizone - Cross (By Mr. Darken)

1 **A.** Yes, sir.

2 **Q.** Okay. All right. Now, Mr. Feran asked you, and you
3 read part of what the pharmacist is supposed to do if he has
4 a concern. Correct?

09:24:51 5 **A.** Yes, sir.

6 **Q.** And that is if any of the criteria in 2 is met, the
7 pharmacist shall, A, require that the person to who the
8 medication is dispensed provide picture identification, and
9 the pharmacist should photocopy such picture identification
09:25:09 10 for the pharmacist's record; correct?

11 **A.** Yes, sir.

12 **Q.** Now, in this case, sir, are you aware that these
13 USMeds patients before they ever got to Mr. Darji they had
14 provided photo identification?

09:25:20 15 **A.** Yes, sir.

16 **Q.** You knew that?

17 **A.** Yes, sir.

18 **Q.** Are you aware that the website made people in certain
19 cases resend their photo identification if the original
09:25:34 20 photo identification was blurry or didn't look right? Are
21 you aware of that?

22 **A.** No, sir.

23 **Q.** You weren't told that?

24 **A.** No, sir.

09:25:40 25 **Q.** Okay. All right.

Catizone - Cross (By Mr. Darken)

1 MR. DARKEN: Your Honor, I move for the add
2 vision of VD-7.

3 MR. FERAN: No objection, Judge.

4 THE COURT: It shall be admitted.

09:25:56 5 Q. Now, looking at the other document, Darji EEEE -- I
6 don't know how E's -- EEEEEEE, I'm sorry, that is Florida
7 Administrative Code 64 B 8-9.014, Standards For Telemedicine
8 Prescribing Practice. Correct?

9 A. Yes, sir.

09:26:15 10 Q. All right. And this is a document which states in
11 Section 1, "Prescribing medications based solely on
12 electronic medical questionnaire constitutes the failure to
13 practice medicine with that level of care, skill, and
14 treatment which is recognized by reasonably prudent
09:26:40 15 physicians being acceptable under similar conditions and
16 circumstances, as well as prescribing legend drugs other
17 than in the course of a physician's professional practice,"
18 right?

19 A. Yes, sir.

09:26:53 20 Q. All right. Now, it doesn't say -- it says based
21 solely on electronic medical questionnaire. Correct?

22 A. Yes, sir.

23 Q. Now, you understand that this case does not involve
24 simply solely based on a medical questionnaire because
09:27:08 25 there's the questionnaire and then there's consultations,

Catizone - Cross (By Mr. Darken)

1 telephone consultations, correct?

2 **A.** The telephone consultations weren't valid in my
3 opinion, sir.

4 **Q.** Okay. My question -- all right. Let me ask it this
09:27:25 5 way: This case doesn't involve solely electronic medical
6 questionnaires; isn't that right?

7 **A.** Well, you would say yes, I would say no.

8 **Q.** Okay. Fair enough.

9 MR. DARKEN: Your Honor, at this time move for
09:27:42 10 the admission of Darji EEEEEEE.

11 THE COURT: Any objection?

12 MR. FERAN: No objection, Judge.

13 THE COURT: It shall be admitted.

14 **Q.** Okay, sir, we're getting to the end. You testified in
09:28:01 15 response to Mr. Feran that federal law defers to state law
16 to actually define what is a valid script.

17 **A.** Yes, sir.

18 **Q.** I'll show you what's marked for identification as
19 VD-6.

09:28:36 20 **A.** Thank you.

21 **Q.** VD-6 is the section of the Code of Federal
22 Regulations, 21 C.F.R. 1306.21, which is titled Requirement
23 of Prescription, correct?

24 **A.** Yes, sir.

09:29:22 25 **Q.** This is the federal law that you were referring to

Catizone - Cross (By Mr. Darken)

1 when you said federal law defers to state law to define what
2 is a valid script. Correct?

3 **A.** No, sir.

4 **Q.** No, it's not?

09:29:34

5 **A.** No, sir.

6 **Q.** What were you talking about?

7 **A.** I'm talking the Food, Drug, and Cosmetic Act which
8 differentiates between prescription drugs, and prescription
9 drugs in the Food, Drug, and Cosmetic Act, the prescription
10 drug can only be dispensed upon a valid prescription. I was
11 referring to that, sir.

09:29:46

12 **Q.** Okay. Well, this section states, Section A, "A
13 pharmacist may dispense directly a controlled substance
14 listed in Schedule III, IV, or V, which is a prescription
15 drug as determined under the federal Food, Drug, and
16 Cosmetic Act only pursuant to either a written prescription
17 signed by a practitioner or a facsimile of a written signed
18 prescription transmitted by the practitioner or the
19 practitioner's agent to a pharmacy or pursuant to an oral
20 prescription made by an individual practitioner and promptly
21 reduced to writing by the pharmacist containing all the
22 information required in Section 1306.05 except for the
23 signature of the practitioner." Correct?

09:30:03

09:30:23

24 **A.** Yes, sir. That's the reference that they're referring
25 to, the same one I used yesterday.

09:30:37

Catizone - Cross (By Mr. Darken)

1 **Q.** All right. So here is my point. Nothing in 1306.21
2 defines what a valid prescription is, correct?

3 **A.** It refers you to the Food, Drug, and Cosmetic Act, and
4 that definition is there. It incorporates that reference
09:31:02 5 and that federal law and that definition.

6 **Q.** Well, actually, sir, let's blow this up.

7 MR. DARKEN: Your Honor, I move for the
8 admission of Exhibit VD-6.

9 THE COURT: Any objection?

09:31:15 10 MR. FERAN: No objection, Judge.

11 THE COURT: It will be admitted.

12 THE WITNESS: My screen is not working.

13 MR. DARKEN: I'll fix the screen. That's my
14 fault. Can you read it now, sir?

09:31:37 15 THE CLERK: It's not on.

16 THE WITNESS: I keep getting ESPN. That's
17 okay. I can read off the page here if that would be easier.

18 MR. DARKEN: One moment, Your Honor.

19 THE COURT: Sure.

09:32:29 20 THE CLERK: It's not working, Judge.

21 THE COURT: It's not working?

22 THE CLERK: No.

23 THE WITNESS: I can read off the sheet, that's
24 fine.

09:32:35 25 **Q.** Okay, if you can read it. I've got a section

Catizone - Cross (By Mr. Darken)

1 highlighted.

2 **A.** If you can read the highlighted section, that would be
3 fine.

09:32:46

4 **Q.** Okay. The highlighted section is, it begins on the
5 third line of 1306.21, and the highlighted section is
6 Prescription Drug as Determined under the Federal Food,
7 Drug, and Cosmetic Act. That's what I've highlighted.

8 **A.** Yes, sir.

09:33:09

9 **Q.** So here is my question. Isn't it true that 1306.21
10 refers to a prescription drug as determined under the
11 Federal Food, Drug, and Cosmetic Act? Correct?

12 **A.** Yes, sir.

09:33:28

13 **Q.** But isn't it also true that what's being defined in
14 relation to the Federal Food, Drug, and Cosmetic Act is what
15 is a prescription drug, not what is a prescription? Isn't
16 that true?

09:33:47

17 **A.** I can't answer the question because I'm not sure what
18 the question is. Under the Food, Drug, and Cosmetic Act a
19 prescription drug is defined, and that definition includes
20 the term valid prescription that defines how it can't be
21 dispensed, so it is part of the definition, sir.

09:34:12

22 **Q.** Well, let me put it this way. 1306.21 does not say
23 that a valid prescription -- to be a valid prescription it
24 has to be a prescription that was issued by a doctor who had
25 conducted a face-to-face physical examination or

Catizone - Cross (By Mr. Darken)

1 face-to-face physical consultation. Correct?

2 **A.** Correct.

3 **Q.** Okay.

4 MR. DARKEN: One moment, Your Honor. Your
09:34:41 5 Honor, I've been handed -- one moment. I've been handed a
6 McKinney vs. Schlatter case that the witness and the
7 government wanted to see the full case. I don't know if
8 he's going to need a little time to read it. I've got one
9 other thing to cover. I don't know how you want to deal
09:35:10 10 with this.

11 THE COURT: Well, I mean, how long is the
12 case?

13 MR. DARKEN: Nine pages.

14 THE COURT: Why don't you finish your other
09:35:24 15 area, I'll give you leave to come back with that one case so
16 we can keep it moving, and maybe at a break he can look at
17 it and counsel for the United States can look at it, and
18 we'll see where we are.

19 MR. DARKEN: That makes sense, Your Honor.

09:35:49 20 **Q.** Okay. You testified in the case of United States
21 versus Christopher Smith in Minnesota on November 15, 2006,
22 correct?

23 **A.** Yes, sir.

24 **Q.** And you were asked questions about the regulation we
09:36:24 25 just looked at, 21 C.F.R. 1306.21. Correct?

Catizone - Cross (By Mr. Darken)

1 **A.** Yes, sir.

2 **Q.** Excuse me?

3 **A.** Yes, sir.

4 **Q.** All right. Do you recall making this question and
09:36:37 5 this answer.

6 "Q. Well, if I wanted to run an Internet pharmacy and
7 I read this regulation, would you agree with me that there's
8 no place here that refers me within this regulation to state
9 law?

09:36:50 10 **A.** Yes, sir."

11 Do you remember that?

12 **A.** Yes, sir.

13 **Q.** Okay. Do you remember we were talking earlier this
14 morning about the part of your website, your organization's
09:37:08 15 website, that has the news on it? Do you remember that?

16 **A.** Yes, sir.

17 **Q.** Okay. And I'm going to show you what's marked for
18 identification as VD-9. That's a news item from your
19 website that was reprinted from the January 2007 Minnesota
09:37:45 20 Board of Pharmacy Newsletter. Is that correct?

21 **A.** Yes, sir.

22 **Q.** And that document refers to the same four elements
23 that were in Government's Exhibit 976, correct?

24 **A.** Yes, sir.

09:38:06 25 **Q.** And that document states, "A patient completing a

Catizone - Cross (By Mr. Darken)

questionnaire that is reviewed by a physician working on behalf of an Internet pharmacy does not constitute a bona fide doctor-patient relationship, and any prescriptions generated as a result of the questionnaire are not valid."

09:38:30 Correct?

6 **A.** Yes, sir.

7 **Q.** All right. And that is dated January 1, 2007,
8 correct?

9 **A.** Yes, sir.

09:38:36 10 MR. DARKEN: Your Honor, I move for the
11 admission of VD-9.

12 MR. FERAN: No objection.

13 THE COURT: It shall be admitted.

14 MR. DARKEN: One moment, Your Honor.

09:38:44 15 THE COURT: Sure.

16 MR. DARKEN: Your Honor, Ms. Wilson informs me
17 that I didn't move for the admission of the Hawaii statute,
18 FFFFFFFF. I move for the admission of the FFFFFFFF document.

19 MR. FERAN: Judge, we have no objection to any
09:39:15 20 state statutes that Mr. Darken wants to introduce.

21 MR. DARKEN: Thank you.

22 THE COURT: It shall be admitted.

23 **Q.** Are you aware, sir, that the New York State Board for
24 Professional Medical Conduct has issued a statement on
09:39:52 25 telemedicine dated December 24, 2003?

Catizone - Cross (By Mr. Darken)

1 **A.** No, sir.

2 **Q.** Okay. Would it change your opinion if you knew that
3 that statement stated that the fact that an electronic
4 medium is utilized for contact between parties or as a
09:40:09 5 substitute for face-to-face consultation does not change the
6 standards of care? Does that change your opinion?

7 **A.** No, sir.

8 **Q.** Would you agree that by using the term" substitute for
9 face-to-face consultation" the New York State Board For
09:40:28 10 Professional Medical Conduct seems to envision some type of
11 non-face-to-face interaction between a doctor and a patient?

12 **A.** Yes, sir.

13 MR. DARKEN: One moment, Your Honor.

14 THE COURT: Sure.

09:41:12 15 **Q.** Are you aware that the Maryland Code 10.32.05.05
16 states that if a physician-patient relationship -- I'm
17 sorry -- as of 2005 states that if a physician-patient
18 relationship does not include prior in-person face-to-face
19 interaction with a patient the physician shall incorporate
09:41:37 20 real time auditory communications or real time visual and
21 auditory communications to allow a free exchange of
22 information between the patient and the physician performing
23 the patient evaluation. Are you aware of that?

24 **A.** No, sir.

09:41:52 25 **Q.** Would that affect your opinion?

Catizone - Cross (By Mr. Gorence)

1 **A.** No, sir.

2 MR. DARKEN: One moment, Your Honor.

3 That's all I have, Your Honor.

4 THE COURT: All right. Who is next?

09:42:09 5 MR. GORENCE: I'm next, Your Honor. Are we
6 going to take a break?

7 THE COURT: No. He's going to come back.

8 CROSS-EXAMINATION OF CARMEN CATIZONE

9 BY MR. GORENCE:

09:42:28 10 **Q.** Mr. Catizone, let me first introduce myself. My name
11 is Bob Gorence, and I represent Barb Rovedo in this case.
12 We've never met, have we?

13 **A.** No, sir.

14 **Q.** Now, I want to start with some background questions in
09:42:57 15 terms of your qualifications. You've told us yesterday that
16 you graduated pharmacy school in '83?

17 **A.** Yes, sir.

18 **Q.** And then you started with the National Association of
19 the Boards of Pharmacy in '85?

09:43:10 20 **A.** Yes, sir.

21 **Q.** Was that full time in '85?

22 **A.** Yes, sir.

23 **Q.** And you've been with them ever since. You got
24 promoted two years later to be the executive director.

09:43:20 25 **A.** Three years later. Yes, sir.

Catizone - Cross (By Mr. Gorence)

1 Q. Three years. So a title that you've then had for the
2 last 24 years.

3 A. Correct.

4 Q. Now, in that capacity as the executive director, I
09:43:30 5 take it you don't practice pharmacy. You're not a
6 practicing pharmacist in a pharmacy now, are you?

7 A. Correct, sir.

8 Q. And you haven't been doing that for how long?

9 A. Probably the last 15 years, sir.

09:43:44 10 Q. So there was a period of time when you were the
11 executive director from '88 on when you did practice as a
12 pharmacist?

13 A. Yes, sir.

14 Q. Okay. One of the things of being of executive
09:43:57 15 director, as Mr. Darken has pointed out for the last hour
16 this morning and yesterday, is that you have a paper trail
17 comparable to a politician in terms of statements that
18 you've made, whether it's testimony in courtrooms or to
19 Congressional boards, or media outlets. And I want to go
09:44:18 20 through the same thing, but I want to highlight some of the
21 issues as they presented in Internet medicine and Internet
22 pharmacies, I should say.

23 Since you've been the executive director this issue
24 of Internet pharmacies really started in the late '90s,
09:44:36 25 didn't it?

Catizone - Cross (By Mr. Gorence)

1 **A.** Yes, sir.

2 **Q.** And in fact, you made quite a few presentations in the
3 late '90s regarding the onset of this new business
4 opportunity as it applied to pharmacies, did you not?

09:44:51 5 **A.** Yes, sir.

6 **Q.** I'm on page 17 of what is your -- and I've highlighted
7 some -- this is your CV.

8 **A.** Excuse me, sir. I don't have access to the computer
9 screen, it's not operating here, so I can't see that.

09:45:40 10 **Q.** I only have one copy.

11 **A.** If you could read the highlighted portions, that would
12 help.

13 **Q.** My question, Mr. Catizone, and I want to start, and
14 you outlined your presentations that you have made to
09:46:21 15 various entities --

16 **A.** Excuse me, sir. What page are you on?

17 **Q.** 17.

18 **A.** Thank you.

19 **Q.** Do you have it? As you've indicated here and in
09:46:36 20 length, really starting in 1999 you started making
21 presentations about this new business opportunity as it
22 presented itself to pharmacists and pharmacies, correct?

23 **A.** I'm sorry, sir, on page 17 I've got chapters and books
24 and publications. I don't have -- that's my page 17 that
09:46:54 25 you gave me. Is it a different page, Your Honor, sir?

Catizone - Cross (By Mr. Gorence)

1 **Q.** I have a report that you dated on December 17, 2008
2 with the CV from that period of time. Is that the newer one
3 he has?

09:47:29

4 **A.** This one has no numbers on it like the one that you
5 have there, sir.

6 **Q.** I'm using your old one. You found it, sir?

7 **A.** Is the first one the Workshop Presentation on Cyber
8 Drug Stores? Is that the first presentation?

09:48:14

9 **Q.** They're not numbered, but they're bullet points, and
10 you've got one, and I've highlighted the first one.

11 **A.** But the one at the top of the page --

12 **Q.** It says Pharmacy Practice, ABC News, with Peter
13 Jennings, you did on May 15 of '02.

09:48:38

14 **A.** I can't locate it, but go ahead, I'm familiar. It's
15 not the same page, sir, but go ahead.

16 **Q.** I'm going to go through this in detail. Do you have a
17 copy of that? I just have a report that was provided to me
18 by the government and was dated December 17 of '07. You
19 addressed it to Ms. Lutzko.

09:48:52

20 MS. LUTZKO: Your Honor, we provided the
21 defense with an updated copy of Catizone's resume this past
22 summer, so I think he maybe handed him two different
23 documents.

09:49:04

24 MR. GORENCE: Well, I marked the old one. I
25 can walk through it, sir. I can see the citations.

Catizone - Cross (By Mr. Gorence)

1 **Q.** Mr. Catizone, I appreciate the new CV, but it was
2 after the dates of this indictment, and I didn't think it
3 was completely relevant, so I'm going to focus on this one.

4 **A.** Yes, sir.

09:49:31 5 **Q.** And all I'm trying to get at with this first set of
6 questions is, as you've indicated, starting in the late '90s
7 this issue of online pharmacies with regulations not yet in
8 place came to the forefront of all pharmacists around the
9 country. That's true, isn't it?

09:49:48 10 **A.** It was an issue, but regulations were in place, sir.

11 **Q.** Come again?

12 **A.** It was true that it was a topic of discussion, but
13 regulations were in place, sir.

14 **Q.** You're saying in 1999 it was completely regulated for
09:50:03 15 pharmacists in terms of how to practice e-pharmacy?

16 **A.** No. The regulation of Internet practice was the same
17 as standard practice back in 1990, sir.

18 **Q.** Well, you made a fair number of presentations about
19 this new field of opportunity that technology was allowing
09:50:20 20 for pharmacists, did you not?

21 **A.** Yes, sir.

22 **Q.** Okay. And as Mr. Darken has gone through, the real
23 issue early on in terms of a problem that you were working
24 with had to do with the importation of drugs from outside
09:50:37 25 the United States. That's true, that was one of the first

Catizone - Cross (By Mr. Gorence)

1 real issues to be addressed with e-pharmacy, Internet
2 pharmacy, correct?

3 **A.** No, sir, that was a different issue. There
4 were -- those are two separate issues.

09:50:53 5 **Q.** Okay. What are you saying? I'm saying the
6 importation was one of the first problems that DEA
7 encountered in the practice of Internet pharmacy. Correct?

8 **A.** I can't speak for the DEA, but from our organization,
9 importation was a separate issue to Internet pharmacy issues
09:51:13 10 that we faced.

11 **Q.** Go ahead and explain, what do you mean by separate
12 issues?

13 **A.** What we saw with the importation was that products
14 were entering the U.S. by citizens traveling to Canada or
09:51:22 15 Mexico and buying those products and transporting them over
16 the border. That became the first problem with importation.

17 It then spread to the use of Internet sites that
18 people ordered from outside of the U.S., but that became
19 then a part of the Internet issue. Importation began before
09:51:43 20 the Internet issue.

21 **Q.** Okay. In your position as the executive director of
22 the National Association of Boards of Pharmacy you work very
23 closely with the DEA, do you not?

24 **A.** Yes, sir.

09:51:54 25 **Q.** And you've actually work closely with federal

Catizone - Cross (By Mr. Gorence)

1 prosecutors around the country?

2 **A.** Yes, sir.

3 **Q.** And it's in addition to just being an expert witness
4 for them, you make presentations to federal prosecutors?

09:52:07 5 **A.** Yes, sir.

6 **Q.** Okay. And in fact, I have a list of at least in 2008,
7 and I've got them on -- it's called the National Advocacy
8 Center, it's in Columbia, South Carolina. You made a
9 presentation to a group of nothing but Assistant U.S.

09:52:24 10 Attorneys, correct?

11 **A.** Yes, sir.

12 **Q.** And you've actually done that since 2008, haven't you?

13 **A.** Yes, sir.

14 **Q.** Tell the jury how many times.

09:52:32 15 **A.** I can't recall, but I was adjunct faculty at Quantico,
16 the training center for the FBI and DEA agents, and so I
17 gave presentations there four times a year, and other
18 meetings when requested.

19 **Q.** So you're actually on the faculty?

09:52:47 20 **A.** As an adjunct, not as a full faculty member.

21 **Q.** As an adjunct. You're not permanently stationed in
22 Quantico?

23 **A.** Correct.

24 **Q.** But you periodically go to teach DEA agents, correct?

09:52:58 25 **A.** Yes, sir.

Catizone - Cross (By Mr. Gorence)

1 **Q.** You indicated yesterday to Mr. Darken you're not paid
2 for that, that's just part of your job is to be in close
3 association with the DEA.

4 **A.** To be in cooperation and to share educational
09:53:12 5 information, sir.

6 **Q.** Okay. And then in addition to that, that role as a
7 teacher, so to speak, about issues about pharmacy, you also
8 testify on their behalf, as Mr. Darken has pointed out --
9 which I don't want to go through all the testimony again --
09:53:28 10 around the entire United States on behalf of the DEA, as
11 well.

12 **A.** Yes, sir.

13 **Q.** Okay. Now, the issue of importation you addressed at
14 some of your presentations, did you not?

09:53:44 15 **A.** Yes, sir.

16 **Q.** I have the second highlighted one. For instance, this
17 one in Arlington Heights, Illinois, in September of 2004,
18 you make a presentation to Illinois pharmacists at their
19 annual conference about the issues in medical importation.

09:54:11 20 **A.** Yes, sir.

21 **Q.** The one at the bottom in '03, the same topic. You're
22 addressing illegal importation of prescription drugs.

23 Again, and that was, as I said, August of '03, you made
24 another presentation about the illegal importation of

09:54:35 25 prescription drugs, that was in Pine Mountain, Georgia, in

Catizone - Cross (By Mr. Gorence)

1 '03. Do you recall that?

2 **A.** Yes, sir.

3 **Q.** Getting back the Internet at the top, you made a
4 presentation in Orlando in '03 having to do with Internet
09:54:57 5 pharmacies, imported pharmaceuticals and regulations,
6 correct?

7 **A.** Yes, sir.

8 **Q.** Now, the issue here as I was talking about was
9 pharmacies not physically located in the United States
09:55:12 10 involved in Internet filling and shipping them in from
11 abroad. That was the issue, correct?

12 **A.** That was the Internet issue, sir.

13 **Q.** I'm focusing on the Internet. I'm not talking about
14 people who go to Mexico and then walk across the border with
09:55:27 15 whatever scripts they want.

16 **A.** Right.

17 **Q.** I'm talking about only in the Internet context, that
18 was a practice in the late '90s, early 2000s, that was of
19 great concern to the DEA. Correct?

09:55:40 20 **A.** Great concern -- I can testify on our behalf, great
21 concern to NABP.

22 **Q.** And as a result of that, and I'm now back on
23 Government's 976, you're familiar with this, I think Mr.
24 Darken showed this to you from the Office of Diversion
09:55:59 25 Control from the DEA. We've all seen it in this trial

Catizone - Cross (By Mr. Gorence)

1 several times, the guidance that was provided in 2001 to
2 doctors and pharmacists, correct?

3 **A.** Yes, sir.

4 **Q.** And in this document it not only detailed at least
09:56:16 5 doctor-patient relationships, which we'll talk about, and
6 I'm on the bottom, where it talked about some pharmacy sites
7 are operating in a foreign country and often do not require
8 any prescription before sending controlled substances to
9 you. And it goes on, these sites often advise that there
09:56:47 10 have been changes to U.S. law that authorize that. And it
11 goes on to say that these sites may be engaging in the
12 illegal sale of controlled substances. Correct?

13 **A.** I don't have the screen, but I trust that you're
14 reading it, so yes.

09:57:05 15 **Q.** The second page of this provided as guidance --

16 MR. FERAN: (Handing.)

17 THE WITNESS: Thank you.

18 **Q.** The second page provides the legal basis then in place
19 in 2001 which prohibited the importation of a controlled
09:57:46 20 substance in the United States, citing 21, United States
21 Code, 952, 953, 954, and the accompanying Code of Federal
22 Regulations; correct?

23 **A.** Yes, sir.

24 **Q.** The second issue that arose early on, and I'm going to
09:58:02 25 go through your publications, where there were foreign sites

Catizone - Cross (By Mr. Gorence)

1 that did not require prescriptions at all from any doctor.
2 You just called up, sent your information, and they would
3 send a prescription without any doctor consultation or
4 questionnaire whatsoever.

09:58:18 5 **A.** Yes, sir.

6 **Q.** Right?

7 **A.** Yes.

8 **Q.** That was the second problem. Maybe we don't have to
9 number them in terms of chronology. We first had the issue
09:58:26 10 of no doctor contact whatsoever with foreign sites or, I
11 should say, foreign pharmacies; then we had the issue of
12 just foreign pharmacies in general. Those were issues that
13 were addressed by DEA in 2001 with regard to being illegal,
14 correct?

09:58:44 15 **A.** No, sir. From our perspective, it was just two issues
16 in that regard. One was the importation of products outside
17 of the U.S., and the most recent example of that was the
18 cancer drugs that were imported from Canada and England that
19 killed a number of people. That was an importation issue we
09:59:06 20 dealt with.

21 The other issue, whether they were U.S. or foreign,
22 was whether there was a valid prescription, and that meant
23 whether there was a doctor consultation or not. Any of the
24 factors you've mentioned we considered under a no
09:59:18 25 prescription, no valid prescription context.

Catizone - Cross (By Mr. Gorence)

1 **Q.** Okay. You recall, and again, I don't have all the
2 presentations, but at least in the top one, on June 17 of
3 2004 I guess you were invited onto NBC's Today Show, and
4 your topic was purchasing medications online without a
09:59:44 5 prescription.

6 **A.** Yes, sir.

7 **Q.** That's the issue that I'm talking about.

8 **A.** Yes, sir.

9 **Q.** Correct?

09:59:48 10 **A.** Yes, sir.

11 **Q.** It wasn't limited to cancer drugs, it also involved
12 scheduled drugs under the Controlled Substances Act,
13 correct?

14 **A.** Correct.

09:59:59 15 **Q.** You addressed a group of governors, a governors Summit
16 on prescription drug importation, this being one of the
17 Senate office buildings. You told them what this issue was
18 in February of '04. Again, same topic, correct?

19 **A.** Yes, sir.

10:00:19 20 **Q.** Again, this being the issue in all of 2004, you went
21 onto a Chicago station -- I only watch the Cubs on that
22 station, I didn't see you -- but it was the importation of
23 prescription drugs; again, the same topic that was raging at
24 that period of time.

10:00:34 25 **A.** Yes, sir.

Catizone - Cross (By Mr. Gorence)

1 Q. Again, whether it was the importation, the ability to
2 get a script with no prescription requirement, this is now
3 in 2003 you're talking about that on CNN. Correct?

4 A. Yes, sir.

10:00:49 5 Q. More presentations about prescription drugs,
6 reimportation, and you're addressing that. You've got
7 importation of drugs from Canada in '03, more topics in the
8 '03 time period, in January Canadian medications. And they
9 weren't limited to just cancer drugs either, were they?

10:01:10 10 A. No, sir.

11 Q. We're talking hydrocodone?

12 A. Every prescription drug, sir.

13 Q. Okay. And what happened is you said, as I pointed out
14 here, laws in place, DEA made it emphatically clear that
10:01:26 15 that's illegal. And I want to use the word emphatic. It
16 was made emphatically clear that you could not obtain a
17 prescription without a valid -- let me backtrack. You
18 couldn't obtain a controlled substance without a valid
19 prescription from a doctor, it was made abundantly clear to
10:01:42 20 every doctor and every pharmacist in the United States as of
21 2004, that was abundantly clear and well known.

22 A. No, the guidance document was issued in 2001, sir.

23 Q. You're talking about the same topics in '03 and '04,
24 so again, the guidance document -- let's go back. At least
10:02:00 25 as of '01 it was clear to every doctor and every pharmacist

Catizone - Cross (By Mr. Gorence)

1 that you couldn't fill -- you could not fill a controlled
2 substance without a valid script, and it couldn't come from
3 a foreign pharmacy. That was made clear, correct?

4 **A.** And the other components about the medical history,
10:02:23 5 the physical examination, and the connection, was made in
6 the 2001 guidance document, too, sir.

7 **Q.** I'm getting there. I'm only taking the topics you
8 talked about in sequence in terms of what the issues were
9 over the last, I want to say, 15 years, when the Internet
10:02:39 10 came into play, and how it evolved.

11 **A.** Uh-huh.

12 **Q.** Then we'll get to this case.

13 **A.** Okay.

14 **Q.** The next issue after imports and no scripts at all
10:02:50 15 really had to do with what Mr. Darken asked you, it was
16 called a questionnaire-based model. No medical records, no
17 doctor consults, just a questionnaire being filled out.
18 That was the next topic that DEA addressed, correct?

19 **A.** It was addressed in 2001. Yes, sir.

10:03:07 20 **Q.** Okay. And if it was addressed, that was a problem at
21 least as of that time, that a model based only on a
22 questionnaire was not going to be sufficient to satisfy the
23 requirements at least as promulgated by most state medical
24 boards as to what constituted a doctor-patient relationship.

10:03:31 25 **A.** Yes.

Catizone - Cross (By Mr. Gorence)

1 **Q.** And DEA addressed it specifically again in 2001, not
2 as law, but as guidance. At least what pharmacists and
3 doctors were told, gave some guidance about what sites may
4 not be legitimate, writing "Some Internet pharmacy sites do
10:04:02 5 not require that you have a prescription from your doctor."
6 We've already talked about that.

7 "These Internet pharmacies require the customer to
8 complete a medical questionnaire," and it goes on, "and
9 sometimes if you don't even answer the question you get a
10:04:17 10 default that allows you to proceed." DEA at the end says
11 "Questionnaire-based models" -- again, just giving
12 guidance -- "may be engaging in the illegal sales of
13 controlled substances."

14 So again, we go from no script, foreign pharmacies,
10:04:36 15 to a model based only on a questionnaire. DEA at least as
16 of 2001 has provided notice to the world that they think
17 there may be a problem with that. Not law, but may be a
18 problem, and I want to underscore the word "may." Correct?

19 **A.** Yes, sir.

10:04:58 20 **Q.** Now, this document in 2001 talked about the
21 doctor-patient relationship, and Mr. Darken showed you on my
22 copy, which was marked up, didn't require face-to-face,
23 there was no requirement of a face-to-face
24 requirement -- excuse me -- face-to-face meeting between
10:05:19 25 doctors and patient to establish this relationship, did it?

Catizone - Cross (By Mr. Gorence)

1 **A.** No, sir. It says a physical examination has been
2 performed. That has to be face-to-face.

3 **Q.** By some doctor, it doesn't say the doctor prescribing
4 it. So if medical records -- you agree that medical records
10:05:37 5 that would have been supplied show that there has been at
6 least one face-to-face between a doctor and a patient. It
7 doesn't say anything in here about the doctor prescribing it
8 has to have a face-to-face, does it?

9 **A.** I believe it does later in the document.

10:05:52 10 **Q.** You take your time and read it.

11 **A.** Okay. The few paragraphs just above page 3 of 6, it
12 says, "Federal law requires that a prescription for a
13 controlled substance to be effective must be issued for a
14 legitimate medical purpose by an individual practitioner
10:06:16 15 acting in the usual course of his professional practice.
16 Every state separately imposes the same requirement under
17 the laws.

18 "Under federal and state law, for a doctor to be
19 acting in the usual course of professional practice there
10:06:29 20 must be a bona fide doctor-patient relationship." And then
21 it continues, "For the purposes of state law, many state
22 authorities" -- and then they define what is a bona fide
23 patient relationship. So it says for a prescription to be
24 valid and effective a bona fide relationship, here are the
10:06:46 25 components of the bona fide relationship, and it explicitly

Catizone - Cross (By Mr. Gorence)

1 says that every state separately imposes the same
2 requirement under its laws.

3 **Q.** Okay. And the point being, and Mr. Darken has gone
4 through in great detail the requirement of a face-to-face in
10:07:02 5 every state was evolving from 2001 until ultimately the
6 passage of the Ryan Haight Act that went into effect after
7 this indictment. That's the reality, as was painstakingly
8 pointed out by Mr. Darken with you in the last hour and a
9 half. Every state changed in terms of when and if it
10:07:25 10 required a face-to-face requirement before establishing a
11 doctor-patient relationship. That's true?

12 **A.** No, sir.

13 **Q.** Okay. Why do you say that? As we just went -- I
14 don't want to go through the whole thing. You stated as of
10:07:40 15 2001 there was a national -- a face-to-face requirement in
16 every state?

17 **A.** Yes, sir.

18 **Q.** What is your basis for that?

19 **A.** The examples that Mr. Darken provided -- and last
10:07:51 20 night I conducted research, and I erred yesterday in court,
21 I indicated that only 20 states between 2001 and 2005 had
22 regulations. Upon further research of that database I've
23 identified 22 states. I have the citations I can provide to
24 counsel of the practice act and regulations.

10:08:09 25 Prior to 2001 within the practice acts and within the

Catizone - Cross (By Mr. Gorence)

1 statutes of both the pharmacy board and medical board that
2 standard existed. The examples that Mr. -- the other
3 attorney gave, some of those took the board regulation,
4 codified them into the statute, and also added products like
10:08:29 5 Soma and other products so it covered more than just the
6 traditional controlled substances.

7 In many of the cases that he cited the laws existed
8 because they were the same for Internet practice and
9 traditional brick and mortar practice, but there wasn't
10:08:43 10 specific laws identifying Internet pharmacies, and so they
11 took painstaking efforts to say the laws exist and cover all
12 pharmacies, but we're going to make sure everybody knows for
13 certain that Internet pharmacies are part of that so there's
14 no question. So it was a further codification, it was
10:08:58 15 another tool that the states employed. But I do have the
16 citations for those 22 states that the other attorney asked
17 for yesterday, sir.

18 **Q.** Okay. And if it was so abundantly clear, what you
19 just testified, I take it you haven't made that statement --
10:09:17 20 I want to go back -- in any of your other testimony in any
21 other case in any federal courtroom in the United States,
22 have you?

23 **A.** Not that I -- I may have, sir. I can't recall.

24 **Q.** And if it was so abundantly clear as to what was
10:09:29 25 required, that face-to-face requirement, you know that the

Catizone - Cross (By Mr. Gorence)

1 DEA never amended this April 27, 2001 guideline giving
2 guidance about what the law says to pharmacists and doctors.
3 This wasn't amended in the time period that we're dealing
4 with, which would go through February of '09.

10:09:52 5 **A.** It happens all the time, sir. Yes. It happens with
6 other issues.

7 **Q.** We're just talking about fair notice. I'm talking
8 about DEA then, it was so clear to you, you'd agree that in
9 eight years they never even give, not law, guidance
10:10:06 10 published in the Federal Register as to what you just said.
11 That never happened, did it?

12 **A.** I didn't -- the guidance that they provided was
13 published and was information provided to all registrants.

14 **Q.** Let me ask the question.

10:10:20 15 **A.** I'm sorry, I didn't understand.

16 **Q.** I'm talking about that an agency of the federal
17 government, the DEA, responsible for enforcing the Food,
18 Drug --

19 **A.** -- and the Controlled Substances Act.

10:10:30 20 **Q.** -- and Controlled Substances Act, they never amended
21 this notice to pharmacists and doctors to reflect what your
22 opinion is here.

23 **A.** Because it already exists in state law, sir.

24 **Q.** In this case you mentioned my client's name, Barb
10:10:58 25 Rovedo. You know that Ms. Rovedo never operated a pharmacy,

Catizone - Cross (By Mr. Gorence)

1 nor dispensed drugs?

2 **A.** Yes.

3 **Q.** I take it you know something about Ms. Mendel and Mr.
4 Mann? They owned the business before that, MS Networks?

10:11:14 5 **A.** I'm not familiar with them, sir.

6 **Q.** You never heard about them at all in this case?

7 **A.** Not -- I can't recall the doctors. I remember the
8 Delta Health, the center, and the involvement there. That's
9 as far as I remember, sir.

10:11:27 10 **Q.** This document has been marked both by the government
11 as 999 and by Mr. Darken, this being the Federation of State
12 Medical Boards of the United States. I take it your
13 organization works with this federation, as well?

14 **A.** Yes, sir.

10:11:46 15 **Q.** And you're familiar with this, are you not?

16 **A.** Yes, sir.

17 **Q.** Now, this came out in 2002, and this was read in part,
18 but I want to go over a little bit what Mr. Darken asked
19 you. The question about guidance again, and it just says,

10:12:29 20 "The relationship between a doctor and patient is clearly
21 established when the physician agrees to undertake a
22 diagnosis and treatment of the patient" -- the patient has
23 to agree, of course; and this question -- "whether or not
24 there has been a personal encounter between the physician or
10:12:50 25 other supervised health care practitioner and the patient.

Catizone - Cross (By Mr. Gorence)

1 I want to focus, this other supervised health care
2 practitioner, that would mean a physician's assistant or a
3 nurse of some sort?

4 **A.** Yes, sir.

10:13:01 5 MS. LUTZKO: Your Honor, may I approach the
6 witness so he can see the exhibit he's referring to.

7 MR. GORENCE: I keep forgetting you don't have
8 it.

9 THE COURT: You may.

10:13:11 10 THE WITNESS: Thank you.

11 **Q.** Mr. Catizone, that is on page 4.

12 **A.** Yes, Section 3.

13 THE COURT: Do you want to ask a few
14 questions, or we can take a break now. We're pretty close.

10:13:21 15 MR. GORENCE: This would be a good time, Your
16 Honor. Briefly. Thank you.

17 THE COURT: Why don't we take 15 minutes.

18 (Recess had.)

19 (Proceedings in the presence of the Jury:)

10:37:15 20 THE COURT: Sir, you're still under oath. Do
21 you understand?

22 THE WITNESS: Yes, sir.

23 THE COURT: All right. Mr. Gorence.

24 MR. GORENCE: Thank you, Your Honor.

10:37:21 25 **Q.** Mr. Catizone, have you had a chance to review this

Catizone - Cross (By Mr. Gorence)

1 over the break?

2 **A.** Yes, sir.

3 **Q.** Again, as of 2002, at least from the physician's side
4 of the equation, in terms of whether or not you needed a
10:37:53 5 face-to-face doctor-patient relationship and there had to be
6 a face-to-face encounter before a doctor-patient
7 relationship, you can see that wasn't required. Do you
8 agree with that?

9 **A.** To some extent, yes, sir.

10:38:08 10 **Q.** Okay. I'm not here to restrict your answers.

11 **A.** Sure.

12 **Q.** I'm going to go to the next page, where you are
13 talking about what, treatment?

14 **A.** In that particular instance that was carved out so
10:38:21 15 that legitimate telemedicine practice could occur. That's
16 why that was in there. But for all other prescribing and
17 diagnosis, the face-to-face physical examination would be
18 required.

19 **Q.** Okay. Well, I want to really focus on the language
10:38:35 20 here. And of course, you're a pharmacist, you're not a
21 doctor.

22 **A.** Correct, sir.

23 **Q.** And this is the portion that was read in yesterday
24 about treatment, and it does have the line right here, it
10:38:46 25 says, "Treatment, including issuing a prescription, based

Catizone - Cross (By Mr. Gorence)

1 solely on an online questionnaire or consultation does not
2 constitute an acceptable standard of care."

3 I want to take that apart for a second, because this
4 is what I was asking earlier. The problem related to a
10:39:06 5 questionnaire-based Internet pharmacy model, this addresses
6 that, correct?

7 **A.** Yes, sir.

8 **Q.** And even the idea that a doctor consult looking at a
9 questionnaire would be insufficient, correct?

10:39:20 10 **A.** Yes, sir.

11 **Q.** But this doesn't address a model that developed having
12 to do with medical records, assuming they're true and
13 authentic, not with government sting, but people like Miss
14 Schiffbauer and Miss Bruce, Wendy Bruce, when they actually
10:39:37 15 submitted real medical records from real doctors having
16 followed from real face-to-face consultations, this doesn't
17 address that in any way, does it?

18 **A.** No, sir. Legitimate telemedicine is not addressed.

19 **Q.** Well, that's what I'm talking about. People that had
10:39:54 20 actually seen doctors and then had gone to another doctor in
21 a telemedicine context, this does not prohibit that
22 explicitly, does it?

23 **A.** Correct, sir.

24 **Q.** Now, lastly, if you had a doctor, and I'll give you a
10:40:11 25 hypothetical, because you're an expert here and I can do

Catizone - Cross (By Mr. Gorence)

1 that, if there was a doctor, and I think there will be
2 testimony here from Dr. Dora, that instead of actually
3 reviewing the medical records herself as a trained
4 physician, if that was delegated not even to a nurse or a
10:40:29 5 physician's assistant but let's say a neighbor or her
6 sister, individuals who had no health care experience
7 whatsoever, that clearly would violate the things set forth
8 here because a doctor was never involved. Correct?

9 **A.** Yes, sir.

10:40:47 10 **Q.** Point being, if a doctor did that and violated the
11 law, a pharmacist would have no way of knowing that, would
12 they, with a valid script submitted by a doctor with a DEA
13 license, the point being doctors could pull the wool over
14 the eyes of a pharmacist at any time. Right?

10:41:06 15 **A.** Yes, sir.

16 **Q.** And the same would be true for a company that all it
17 did was submit medical records to the doctor. In this case
18 you know that's what Miss Rovedo's company did, Delta
19 Health?

10:41:17 20 **A.** Sure. It's possible, sir, yes.

21 **Q.** The point -- no, it's not just possible. Delta Health
22 once they submitted the records online, you know from what
23 you've seen in this case they were not part of the online
24 consultation nor medical review process, was it?

10:41:34 25 **A.** From what I saw, I believe that they were involved in

Catizone - Cross (By Mr. Gorence)

1 establishing the doctor relationships and setting up the
2 explanations for the consultations and designing it, but I'm
3 not sure where they were in terms of the review of the
4 medical records, sir.

10:41:51 5 **Q.** Let's make sure we're on the same page. Delta Health
6 collected a driver's license or form of identification,
7 always a driver's license, from the patients. You know
8 that?

9 **A.** Yes, sir.

10:42:03 10 **Q.** And as Mr. Darken indicated, if the driver's license
11 was not valid or wasn't legible enough it was sent back as
12 the first step. That was what was required, is a valid
13 driver's license showing the identity of someone who
14 actually existed.

10:42:20 15 **A.** Yes, sir.

16 **Q.** And you know, as we can see here, even on the very
17 last attempt by Diversion Investigator Zakrzewski on
18 December 10 of '07 they tried to send in a phony one, one
19 that was clearly patently not valid, and it was rejected by
10:42:38 20 Delta Health. You can see it right there on the chart, on
21 behalf of Matthew Douglas.

22 **A.** Sure. Based on the chart, yes, sir.

23 **Q.** Okay. Then I'm saying Delta Health after that
24 collected medical records that were either e-mailed or
10:42:50 25 faxed, and then all they did is submit them on to the

Catizone - Cross (By Mr. Gorence)

1 physician. I take it that's your understanding of this
2 case, isn't it, from the materials you reviewed?

3 **A.** No, sir.

4 **Q.** Explain yourself.

10:43:00 5 **A.** It was my understanding that Delta Health selected the
6 physicians and even directed the physicians in terms of how
7 they should consult the time, and then it was Delta Health
8 in recorded conversations that suggested changing the model
9 from working with pharmacies to actually issuing a
10:43:18 10 prescription so the patients could then take those to
11 various pharmacies. So it seemed like Delta Health was
12 involved in the organization and operation to a much larger
13 extent than just simply passing the records on, sir.

14 **Q.** There were 3,000 recorded captured phone calls. Did
10:43:32 15 you listen to -- you said you didn't listen to a single one
16 of them?

17 **A.** No, sir. I just read the information in the report
18 about some of those conversations.

19 **Q.** And you indicated you never even read the actual
10:43:41 20 transcripts of these recorded conversations, correct?

21 **A.** Correct sir.

22 **Q.** And all you're doing is relying on the hearsay of what
23 an agent wrote about some of them, now we use the word
24 snippets? That's what you're basing this on, not even
10:43:53 25 firsthand information. You are just relying on the hearsay

Catizone - Cross (By Mr. Gorence)

1 of an agent as to what occur without listening to any of it?

2 **A.** The information in the report, yes, sir.

3 **Q.** So again, this is twice removed. You've never even
4 taken the time before you want to come in and say this to a
10:44:06 5 jury to listen to them yourself or read them?

6 **A.** I haven't done that, sir. Yes.

7 **Q.** Let me get back to my first question. You've already
8 admitted that if the doctors didn't engage in something that
9 was legitimate, i.e. a legitimate doctor-patient
10:44:21 10 relationship, you can fool the pharmacists of the world,
11 right?

12 **A.** Sometimes, yes, sir.

13 **Q.** And in this case Delta Health, assuming that they just
14 submitted the records off -- well, let me ask -- you know
10:44:34 15 Delta Health didn't participate in a three-way conversation
16 between the doctor, the patient, and a representative from
17 Delta Health during the doctors' consultation. You know
18 that, don't you?

19 **A.** Yes, sir.

10:44:48 20 **Q.** Okay. So after they passed the medical records off,
21 the ultimate decision of either approving or disapproving
22 that prescription was solely with the doctor.

23 **A.** Yes, sir.

24 **Q.** And if the doctor approved it, Delta Health had
10:45:05 25 nothing to do with that.

Catizone - Cross (By Ms. Rha)

1 **A.** Yes, sir.

2 MR. GORENCE: I have nothing further, Your
3 Honor.

4 THE COURT: Ms. Rha?

10:45:16 5 MS. RAH: Thank you, Judge.

6 CROSS-EXAMINATION OF CARMEN CATIZONE

7 BY MS. RHA:

8 **Q.** Good morning.

9 **A.** Good morning.

10:45:50 10 **Q.** Good morning. Can you hear me?

11 **A.** Yes.

12 **Q.** Good morning, Mr. Catizone. My name is Megan Rha, and
13 I'm one of the attorneys representing Dr. Terence Sasaki in
14 this case. Okay? And a lot has been asked of you and
10:46:07 15 you've given a lot of answers, so I am going to try to not
16 repeat some of the things that's already been covered. So I
17 am just going to go through some of the things you said
18 during your direct examination that perhaps wasn't followed
19 up, and just ask you some follow-up questions on that.

10:46:24 20 Okay?

21 **A.** Sure.

22 **Q.** You started by responding to Mr. Feran's questions
23 with respect to your background, and you started by saying
24 how you've been the executive director of this particular
10:46:38 25 organization that you represent here today that's the

Catizone - Cross (By Ms. Rha)

1 National Association of Boards of Pharmacy, correct?

2 **A.** Yes.

3 **Q.** And you've been with that organization since 1985, and
4 executive director since 1988, correct?

10:46:53 5 **A.** Correct.

6 **Q.** And now with respect to this organization, which I
7 will call NABP, NABP, you stated that the members of this
8 organization are state Boards of Pharmacy and the equivalent
9 of state boards in Canada, Australia, New Zealand, correct?

10:47:14 10 **A.** And South Africa.

11 **Q.** And South Africa. So including Canada, Australia, New
12 Zealand, South Africa, that's four countries and 50 state
13 boards from this country that make up the members of your
14 organization?

10:47:29 15 **A.** Yes. Puerto Rico, the District of Columbia, Guam,
16 Virgin Islands, all the territories, as well, so there's
17 probably about 57 members.

18 **Q.** Okay. Thank you. And you stated as part of your
19 response to one of the questions initially that only state
10:47:45 20 agencies that regulate pharmacy are members of your

21 organization, but not individuals who are not pharmaceutical
22 companies. Do you remember giving that answer, sir?

23 **A.** I didn't hear the last part. The pharmaceutical --

24 **Q.** Not pharmaceutical companies and not individual
10:48:07 25 pharmacists?

Catizone - Cross (By Ms. Rha)

1 **A.** Correct.

2 **Q.** Correct? So they are not part of the national
3 association of Boards of Pharmacy because obviously, as the
4 name states, your organization, NABP, is made up of other
10:48:19 5 boards that actually regulate pharmacists and pharmacies.

6 Am I right? Am I understanding?

7 **A.** Yes.

8 **Q.** And now, is that because your organization NABP is
9 actually involved in regulating, supervising, overseeing
10:48:42 10 pharmacists and pharmacies that exist in this country?

11 **A.** No, it's because we assist the states in that process.
12 We're not directly involved and have no authority or
13 government standing.

14 **Q.** You make recommendations to state boards that regulate
10:48:58 15 them though?

16 **A.** Yes.

17 **Q.** And would it also be fair and correct for me to
18 understand your organization NABP to be fair and impartial
19 and independent?

10:49:08 20 **A.** Yes.

21 **Q.** And you also stated that your organization NABP does
22 not lobby. Do you remember saying that?

23 **A.** Yes.

24 **Q.** Now, when you gave that answer, what did you mean by
10:49:22 25 the fact that your organization does not lobby?

Catizone - Cross (By Ms. Rha)

1 **A.** There are very specific requirements at the federal
2 level and state level that if you're going to participate in
3 lobbying activities that you have to register and designate
4 individuals as lobbyists. We do not have or fall under any
10:49:37 5 of those requirements, nor do we hold any registered
6 lobbyists in any state or with the federal government.

7 **Q.** So I understand that NABP is not registered as a
8 lobbying organization, but when you use the word, and you
9 volunteered this answer to Mr. Feran, because it triggered
10:49:54 10 something in my mind, you said your organization does not
11 lobby, that it only is involved in charitable and
12 educational activities.

13 **A.** Correct.

14 **Q.** Right? So when you use that word lobby, I understand
10:50:08 15 now that NABP is not registered as a lobbying organization,
16 but what do you mean they don't lobby?

17 **A.** We don't specifically advocate passage of a particular
18 bill unless asked our opinion. We don't meet with
19 individual congressmen or senators or state legislators
10:50:30 20 unless invited to do so or requested to do so and requested
21 to give our opinion on a legislation, or unless the states
22 indicate to us through a resolution or recommendation that
23 we should advance a position saying that the states are in
24 favor of this or the state Boards of Pharmacy are in support
10:50:45 25 of a particular bill, legislation, or activity.

Catizone - Cross (By Ms. Rha)

1 **Q.** I see, Mr. Catizone. So the difference here, and
2 correct me if I'm wrong, is that if you are asked or if you,
3 Mr. Catizone, or if your organization NABP is asked by a
4 Congressional member or asked by a senator or asked by
10:51:09 5 somebody involved in the legislative process, if they ask
6 you for your opinion, your recommendation, your comments,
7 you could provide them, but you cannot go before them and
8 solicit your involvement and your participation. Is that
9 your understanding of what NABP does and does not do?

10:51:28 10 **A.** Right. We can't solicit or we can't actively lobby
11 for a particular law or requirement or change.

12 **Q.** But in reality, NABP does get asked, does get
13 solicited, and has many requests for NABP to make comments
14 or to review something and give some sort of feedback, or
10:51:53 15 appear before a Congressional hearing or a subcommittee or
16 committee meetings, and provide NABP's opinions, correct?

17 **A.** Yes.

18 **Q.** And many times when such opinions are given on behalf
19 of NABP, you as the executive director, with all your
10:52:11 20 experience in speaking and writing and testifying, two
21 decades plus of experience, you are the one in fact that
22 appears on behalf of NABP many times to provide such
23 information and opinion, et cetera. Right?

24 **A.** Yes.

10:52:28 25 **Q.** Now, I looked at your CV, I looked at your latest one.

Catizone - Cross (By Ms. Rha)

1 The one that I had ended in 2008, because in 2008 was when
2 Miss Lutzko wrote a letter to you asking for your opinion,
3 right, on this particular matter. Right?

4 **A.** Yes.

10:52:48 5 **Q.** She wrote you a letter dated August 11, 2008, "Thank
6 you for agreeing to provide expert opinion," and then she
7 provided series of documents that she specified in that
8 cover letter that she sent to you. Right, sir?

9 **A.** Yes.

10:53:04 10 **Q.** And along with that I guess either you gave her the CV
11 or she obtained one, one was provided to me, and when I took
12 a good look at your CV, I noticed that as of 2008 you had
13 given over 134 presentations. Does that sound correct?

14 **A.** Yes.

10:53:23 15 **Q.** And then when I looked at your CV as of yesterday, you
16 know, as of 2012, you had given additional presentations in
17 addition to the 134 presentations that I had counted as of
18 2008. Correct?

19 **A.** Yes.

10:53:38 20 **Q.** And when you testified yesterday during
21 cross-examination by Mr. Darken, it also came to my
22 attention that in addition to all the different criminal
23 cases in which you had testified as of 2008, since 2008,
24 from then until now, you've also been involved in additional
10:53:57 25 numerous federal criminal trials, and you have testified on

Catizone - Cross (By Ms. Rha)

1 behalf of the U.S. Attorney's Office; right, sir?

2 **A.** Yes.

3 **Q.** And it also came as a surprise to me that all those
4 times that you testified on behalf of the United States, the
10:54:15 5 government, as their expert witness, that you were never
6 compensated for your time. You're not being compensated
7 today for your time, right?

8 **A.** No.

9 **Q.** And in addition to you being here yesterday and today,
10:54:32 10 and the travel time, I mean, you weren't compensated for any
11 of those hours you spent?

12 **A.** No.

13 **Q.** And what about all these items that you had to review
14 that have been sent to you by this letter dated August 11,
10:54:47 15 2008. You were given an affidavit in support of application
16 for wire interception of James Hazelwood's telephone dated
17 April 19, '07. You reviewed that affidavit?

18 **A.** Yes.

19 **Q.** You were given affidavit in support of application for
10:55:00 20 continued wire interception of James Hazelwood's telephone
21 dated May 18, '07. You obviously reviewed that application
22 and the affidavit?

23 **A.** Yes.

24 **Q.** And you reviewed affidavit in support of application
10:55:12 25 for continued wire interception of James Hazelwood's

Catizone - Cross (By Ms. Rha)

1 telephone dated June 15, '07, you reviewed that, I'm sure?

2 **A.** Everything on the list I reviewed.

3 **Q.** And application and affidavit for search warrant of
4 Julie Toennies' e-mail account, you reviewed that, sir?

10:55:28 5 **A.** Yes.

6 **Q.** And then you also reviewed DEA-6 reports summarizing
7 details of undercover control purchases. And then they go
8 on to list one, two, all the way up to 20 different
9 purchases or attempt to purchase incidents. So you reviewed
10:55:45 10 all the diversion investigator's reports summarizing those
11 buys, correct?

12 **A.** Correct.

13 **Q.** And then you reviewed summary of prescription volume,
14 summary of prescription, another summary of prescription
10:55:58 15 volume, selection of e-mails; all these were reviewed by
16 you?

17 **A.** Yes.

18 **Q.** By the way, the affidavits that were given to you that
19 the government had in the past submitted so they could
10:56:13 20 wiretap Hazelwood's phone call conversations and the
21 affidavit that the government has submitted in the past so
22 they could search Julie Toennies' e-mail, when you read
23 those affidavits you saw that the government laid out the
24 probable cause that they were submitting to the Court so
10:56:33 25 they could get the Court's permission to wiretap somebody's

Catizone - Cross (By Ms. Rha)

1 phone conversation; right?

2 **A.** Yes.

3 **Q.** And the probable cause that they are saying that they
4 had as of that date to say, Judge, please allow me to go
10:56:46 5 search somebody's e-mail account in this case, Julie
6 Toennies, who is the sister and co-defendant with James
7 Hazelwood, correct?

8 **A.** Yes.

9 **Q.** And when you read those affidavits you would agree
10:56:59 10 with me that those affidavits laid out details, right?

11 **A.** I believe so, yes.

12 **Q.** And obviously the Judge saw there was probable cause,
13 because you know that phone conversations were intercepted
14 on wiretaps for April, May, June, and July of 2007, right?

10:57:16 15 **A.** Yes.

16 **Q.** And you also know that the Judge allowed the
17 government to intercept -- not intercept, but go and search
18 Julie Toennies' e-mail account and read her e-mail. You
19 know that, too, right?

10:57:28 20 **A.** Yes.

21 **Q.** But when you were reviewing all these things you did
22 not see Dr. Terence Sasaki mentioned as an actor, correct?
23 You didn't see his name in those affidavits.

24 **A.** Not in the affidavits.

10:57:42 25 **Q.** Right. And you would also agree with me that although

Catizone - Cross (By Ms. Rha)

1 they laid out all the facts that they thought they had as of
2 in 2007, and they laid out the facts, they laid out the
3 facts that would make probable cause, and they would name
4 the targets, they would name the people that they were
10:57:58 5 suspicious of, et cetera, et cetera, that despite all of the
6 details that they believe they sufficiently provided to the
7 Court at that time, my client, Dr. Terence Sasaki, was not
8 named in those documents. Right, sir?

9 **A.** Correct.

10:58:15 10 **Q.** And, sir, did you know, did the government tell you
11 that Dr. Sasaki wrote an e-mail, detailed e-mail to the DEA
12 in May -- excuse me -- in May of 2007?

13 MR. FERAN: I object to this.

14 MS. RHA: Yes. Go ahead, Mr. Feran.

10:58:38 15 MR. FERAN: I objected, Judge.

16 THE COURT: Go ahead. Here is what I would
17 say. Ask him whether or not he has any knowledge about, you
18 know, any certain -- if he doesn't have any knowledge base
19 then you don't get a chance to go through like all the
10:58:56 20 different things that is a part of the evidence.

21 So let's see whether he has any knowledge about
22 anything in regard to what you're talking about. That's how
23 we would start it. And then if he has some knowledge you
24 can go on and testify. If he has no knowledge, then I think
10:59:11 25 that would probably end the inquiry with regard to that.

Catizone - Cross (By Ms. Rha)

1 MS. RHA: Judge, I forgot if I had a question
2 pending, but I'll start again.

3 **Q.** So Mr. Catizone, so the undercover buys, right, that
4 you reviewed in this case, you know, 20 that's mentioned in
10:59:30 5 August 11, 2008, and then I also see there is a cover letter
6 that was sent to you dated September 19 of 2012, like a
7 month ago. Do you remember getting that letter?

8 **A.** Yes.

9 **Q.** And along with that letter, Mr. Catizone, you were
10:59:45 10 given additional DEA-6 reports that has to do with a list, 1
11 through 26, some sort of attempted buy, some sort of
12 purchases, and these documents are date numbered from 1
13 through 9 and to 28. Do you need to look at this to refresh
14 your memory?

11:00:04 15 **A.** No.

16 **Q.** You did spend your time reviewing these documents, as
17 well, right?

18 **A.** Yes, I did.

19 **Q.** And the transcripts of phone conversations,
11:00:10 20 transcripts of recordings. I don't remember if you said you
21 heard the recordings, but anyway, transcripts of the
22 undercover buys, et cetera, right?

23 **A.** Yes.

24 **Q.** And how many hours would you say that you spent
11:00:23 25 approximately reviewing the items that were given to you via

Catizone - Cross (By Ms. Rha)

1 the letter dated August 11 of '08 and via the letter dated
2 September 19 of 2012?

3 **A.** For the first letter 20 hours, for the second letter
4 30 hours.

11:00:37 5 **Q.** So anyway, reviewing all these undercover buy
6 paperwork, undercover buy transcripts of phone calls, and
7 the diversion investigator's report which we call DEA-6
8 reports, related to all these undercover buys, and you would
9 agree with me that the items that you reviewed show that
11:01:14 10 these undercover buys were attempted not within a week span,
11 not within two weeks span, but over a period of time; right?

12 **A.** Yes.

13 **Q.** And during that time that all these attempts were
14 being made and undercover purchases were actually attempted
11:01:31 15 and successfully executed, nowhere in any of that material
16 did you see my client, Dr. Sasaki, Dr. Terence Sasaki's name
17 mentioned; correct?

18 **A.** In the undercover?

19 **Q.** Yes, in the undercover, sir.

11:01:49 20 **A.** No.

21 **Q.** Right?

22 **A.** Correct.

23 **Q.** Right? Okay.

24 MS. RHA: Can I actually, Judge, can I have
11:01:57 25 your permission to move that poster so I can see the board

Catizone - Cross (By Ms. Rha)

1 with all the photos of the people?

2 THE COURT: You want to move it?

3 MS. RHA: Yes. I'll do it, Judge. Can I
4 approach?

11:02:09 5 THE COURT: Sure.

6 MS. RHA: Your Honor, may I have the
7 permission to stand here? I just want to point to some of
8 these photos.

9 THE COURT: Do you have a microphone on?

11:02:39 10 MS. RHA: I do, Judge.

11 THE COURT: You may proceed.

12 BY MS. RHA:

13 **Q.** Now, Mr. Catizone, when you were reviewing all those
14 items that took you 20 hours plus 30 hours, you know?

11:02:47 15 That's a lot of time, I know, because I had to review that
16 too.

17 Now, when you were reviewing those items there were
18 names that appeared in the affidavits for the search
19 warrants for the e-mail account, there were names that
11:02:59 20 popped up in the affidavits that had to do with intercepting
21 Mr. Hazelwood's phone calls; right? And then the undercover
22 buys, samples of actual e-mails that you were given,
23 according to the September 2012 letter.

24 Amongst all these things, the names that popped up,
11:03:19 25 if you would take a look at this poster that was shown to

Catizone - Cross (By Ms. Rha)

1 the jury at the beginning of this case, do you recognize
2 this name, James Hazelwood?

3 **A.** Yes.

4 **Q.** And he's here, and you're also aware that he's named
11:03:35 5 in the indictment, right?

6 **A.** Yes.

7 **Q.** And do you recognize this name, Delta Health?

8 **A.** Yes.

9 **Q.** Do you recognize Edward Cheslow?

11:03:46 10 **A.** Yes.

11 **Q.** Do you recognize Dora Fernandez?

12 **A.** Yes.

13 **Q.** Do you recognize the Medicine Shoppe, Medicom,
14 Liddy's?

11:03:53 15 **A.** Yes.

16 **Q.** These are all -- Liddy, was that included in any of
17 those documents that you saw?

18 **A.** Yes.

19 **Q.** What about Helen Kann?

11:04:01 20 **A.** Yes.

21 **Q.** Julie Toennies?

22 **A.** Yes.

23 **Q.** Jennifer Ryan?

24 **A.** Yes.

11:04:06 25 **Q.** Fiorillo, Derks, USMeds; right?

Catizone - Cross (By Ms. Rha)

1 **A.** Correct.

2 **Q.** All of these, Anthony Trawick, do you remember him?
3 He was in the affidavit for the search warrant, right?

4 **A.** Yes.

11:04:14 5 **Q.** You remember that name, but he's not in the
6 indictment, right? And then one of the undercover buys --

7 MR. FERAN: Judge, I'm going to object to
8 that.

9 THE COURT: Okay. Let me read this.

11:04:39 10 MS. RHA: Can I ask one last question? And
11 I'll be done with this poster board for the duration of
12 Mr. Catizone's cross-examination.

13 THE COURT: Why don't you -- and Mr. Feran can
14 stay on his feet in case he objects. She wants to ask one
11:04:52 15 last question.

16 MS. RHA: One last question.

17 THE COURT: But it doesn't mean I'll let him
18 answer it.

19 MR. FERAN: That's fine, Your Honor.

11:04:59 20 MS. RHA: Thanks.

21 **Q.** Mr. Catizone, so everybody on this board appeared in
22 those documents that you -- you know, the search warrant
23 applications, right, and the affidavits for the phone calls,
24 the e-mail applications, the undercover buys, all the DEA-6
11:05:17 25 reports related to the undercover buys, the transcripts

Catizone - Cross (By Ms. Rha)

1 related to the undercover buys. These people's names
2 appear. The only name that does not appear in those things
3 that I just listed is Dr. Terence Sasaki, correct?

4 **A.** In the documents that you listed?

11:05:34 5 **Q.** That I just listed.

6 **A.** Correct, in just those documents.

7 **Q.** Thank you. So you know, it occurs to me, you spent 50
8 hours reviewing these items, you spent two days testifying
9 here, you spent a day traveling, a day traveling back
11:05:48 10 tomorrow perhaps, but you do not get compensated for these
11 hours. What about the other testimonies that you gave on
12 behalf of the U.S. Attorney's Office in all those other
13 cases that you mentioned, were you compensated for those?

14 **A.** No.

11:06:05 15 **Q.** And prior to you going as an expert witness for those
16 cases I would think that you being an expert on those cases,
17 you would have had to review documents and listen to tapes,
18 or look at prescriptions, or whatever it may be, related to
19 your expert testimony. Correct?

11:06:24 20 **A.** Correct.

21 **Q.** And you weren't compensated for those hours either?

22 **A.** No.

23 **Q.** What about the fees related to you traveling here?

24 Your airfare, your hotel, your meal and lodging, do you get
11:06:38 25 compensated for that?

Catizone - Cross (By Ms. Rha)

1 **A.** My expenses are reimbursed, yes.

2 **Q.** So on an average, in 2012 how many times have you
3 testified in addition to this trial on behalf of the United
4 States, you know, the U.S. Attorney's Office, as an expert
11:06:54 5 witness?

6 **A.** In 2012, I think two additional times, two or three.

7 **Q.** And were they outside of the state where you reside
8 and work?

9 **A.** Yes, yes.

11:07:04 10 **Q.** And what about in 2011, how many times did you testify
11 as an expert witness for the U.S. Attorney's Office?

12 **A.** Between four and five times.

13 **Q.** What about in 2010?

14 **A.** Again, the balance of the 12 times, probably three or
11:07:19 15 four times.

16 **Q.** And I would think that you would have testified in
17 2009, 2008, '7, et cetera?

18 **A.** One or two in 2008, one in 2009.

19 **Q.** And now this is all in addition to the presentations,
11:07:32 20 the talks you give, the seminars you hold, the classes you
21 teach, et cetera, et cetera?

22 **A.** Yes.

23 **Q.** Now, you do hold a very important title in my mind,
24 which is the executive director of the National Association
11:07:48 25 of Boards of Pharmacy. So my question is, what does that

Catizone - Cross (By Ms. Rha)

1 entail, that title? What are your duties and your
2 responsibilities?

3 **A.** I'm responsible for the oversight of the staff and the
4 operation of the association.

11:08:03 5 **Q.** You're responsible for the staff -- I'm sorry -- staff
6 and the operation. So as part of your duties as the
7 executive director, sir, you have regular contact with the
8 state boards that exist in each state of this country?

9 **A.** Yes.

11:08:28 10 **Q.** And you also are in pretty consistent communication
11 with the Drug Enforcement Administration --

12 **A.** Yes.

13 **Q.** -- DEA with respect to controlled substances, and
14 things of that nature?

11:08:40 15 **A.** Yes.

16 **Q.** And I would also think that you as the executive
17 director would also be pretty in good communication,
18 consistent communication with the Federation of State
19 Medical Boards; correct?

11:08:55 20 **A.** Correct.

21 **Q.** And in fact, Federation of State Medical Boards is
22 sort of like the counterpart of NABP but for the doctors,
23 correct?

24 **A.** Correct.

11:09:05 25 **Q.** Medical doctors, I mean.

Catizone - Cross (By Ms. Rha)

1 **A.** And osteopathic doctors.

2 **Q.** I'm sorry?

3 **A.** And osteopathic doctors, as well.

4 **Q.** Correct. DOs. Yes. So but then there's also the

11:09:18 5 American Medical Association. Are you in contact with them

6 as well within your duties as an executive director for

7 NABP?

8 **A.** Yes, but not as frequently.

9 **Q.** Not as frequently, because FSMB, right, the Federation

11:09:37 10 of State Medical Boards are composed of individual state

11 medical boards, correct?

12 **A.** Correct.

13 **Q.** And the individual medical state boards are the

14 agencies that would actually regulate the practices of the

11:09:50 15 doctors within their respective states, correct?

16 **A.** Correct.

17 **Q.** But then the American Medical Association, AMA, is not

18 a -- is a voluntary membership organization for the doctors

19 in this country, right?

11:10:04 20 **A.** Correct.

21 **Q.** Now, you as an executive director of your organization

22 then, it seems to me that -- and you would agree with me, I

23 think -- that you spend a fair amount of time traveling,

24 preparing for, and actually testifying or presenting, or

11:10:29 25 giving testimonies or issuing opinions, all around this

Catizone - Cross (By Ms. Rha)

1 country, right?

2 **A.** Yes.

3 **Q.** And you said in addition to what seems to me like a
4 huge, you know, number of hours you spend doing this, you
11:10:44 5 also spend your time, you said, overseeing the operation of
6 your particular organization, which is the NABP, right?

7 **A.** Correct.

8 **Q.** And as part of overseeing the overall operation of the
9 organization you will be familiar with how your organization
11:11:01 10 gets its money, how much money it uses to operate, where it
11 spends its money, et cetera; right?

12 **A.** Correct.

13 **Q.** Now, I remember when you were talking during direct
14 examination about your organization not lobbying, one of the
11:11:15 15 things you volunteered again was that the IRS
16 something-something, and did you mean that NABP is a
17 501(c)(3) organization?

18 **A.** Correct.

19 **Q.** Now, would you tell the jury what 501(c)(3) is, sir?

11:11:30 20 **A.** It's a classification by the IRS that says that we can
21 engage in charitable and educational activities, and it
22 exempts us from taxes to the IRS because of our activities.
23 Similar to a hospital, similar to a religious organization,
24 similar to those organizations that don't pay taxes because
11:11:48 25 they're involved in charitable and educational works that

Catizone - Cross (By Ms. Rha)

1 support the community and support the government.

2 **Q.** So as a charitable and educational organization that's
3 exempt from taxes, how do you fund yourself? I mean, you
4 testified yesterday that you receive \$450,000 a year, right?

11:12:11 5 And today you testified that you spend enormous number of
6 hours just on this case, you spent 50 hours reviewing
7 documents, and spending days testifying. The only
8 reimbursement you get is for your travel and lodging and
9 meals. How does a charitable organization sustain the work
11:12:30 10 style that you seem to be engaged in for the last 20 years
11 without you being compensated for all these hours that you
12 spend outside of the organization itself?

13 **A.** Two different questions, but I'll answer both of them.

14 **Q.** Thank you.

11:12:44 15 **A.** Our funding comes from really just three sources. The
16 pharmacists who take the national licensure exam pay us the
17 fee, and that exam is about \$450, and every pharmacy student
18 that wants to become a pharmacist has to take that exam
19 because the states require it. They're also required to
11:13:02 20 take a state law exam which we also develop and administer
21 for the states, and that fee is somewhere in the range of
22 about \$200. That's our primary source of income.

23 The other source of income is when a pharmacist wants
24 to transfer from state to state they provide a fee to us for
11:13:19 25 us to do a background check, check all their disciplinary

Catizone - Cross (By Ms. Rha)

1 information, and then provide that information to the
2 states. And that fee is somewhere between 3 and \$400,
3 depending upon how many states the pharmacist wants to
4 transfer their license.

11:13:32 5 So about 60 percent of our revenue comes from our exam
6 fees, which I have used to develop this national exam I
7 administer for the states, which would cost each state a
8 million to 2 million on its own to develop, so it's a
9 savings for the state. 35 percent of our revenue comes from
11:13:51 10 these fees that we charge the pharmacist to do the
11 background check, and then the remainder of our fees come
12 from our accreditation program of the wholesalers and
13 pharmacies that are distributing durable medical equipment.

14 We lose money on our Internet program, we lose money
11:14:06 15 on our annual meeting, we lose money on all our
16 publications, because those are benefits we provide to the
17 states. Every state board of pharmacy since 1985 has paid
18 us a membership fee of \$250, and that's all the states pay
19 for the services we provide.

11:14:23 20 **Q.** Thank you, Mr. Catizone. Now that I know how your
21 organization survives, operates, maintains its operation, I
22 have follow-up question to that. That is that you just
23 stated again, and you said it yesterday, and it just stuck
24 in my head, you were talking about your organization
11:14:49 25 certifying Internet pharmacies. And again, you know, sir, I

Catizone - Cross (By Ms. Rha)

1 don't represent the pharmacy in this case, I represent Dr.
2 Sasaki, but the jury should know. You were talking about
3 the NABP being involved in certifying Internet pharmacies,
4 right?

11:15:08 5 **A.** Yes.

6 **Q.** Do you remember that? And that program, a lot of
7 acronyms in this case, but that program is called VIPPS;
8 correct?

9 **A.** Correct.

11:15:20 10 **Q.** And it stands for Verified Internet Pharmacy Practice
11 Site, correct?

12 **A.** Correct.

13 **Q.** And this is something you or your organization
14 developed in 2000?

11:15:31 15 **A.** 1999 we first launched it.

16 **Q.** 1999?

17 **A.** It began in 1997, we launched it in 1999.

18 **Q.** 1999. So at the onset of the Internet in the
19 e-commerce industry, your organization already foresaw that
11:15:49 20 this would be something that would be necessary and came up
21 with an accreditation program called VIPPS, VIPPS for short;
22 right?

23 **A.** Correct.

24 **Q.** And this program still exists, right?

11:16:03 25 **A.** Yes.

Catizone - Cross (By Ms. Rha)

1 **Q.** And when you were describing it, and you didn't spend
2 much time on it yesterday during your direct examination,
3 you described it briefly and then you said it's a money
4 loser, that your organization is losing money on it; right?

11:16:18 5 **A.** Yes.

6 **Q.** Do you remember saying that?

7 **A.** Yes.

8 **Q.** And then do you remember you just said that just now
9 like a minute ago?

11:16:24 10 **A.** Yes.

11 **Q.** You keep pointing that out, that VIPPS is a program
12 that you started in 1999 -- now I know -- but your
13 organization NABP, which is a charitable organization, keeps
14 on losing money on it. So I looked it up, you know? Like
11:16:40 15 you looked up things last night, I looked up things last
16 night. And when I looked it up what I found was really
17 interesting. And tell me you would agree with me this: As
18 of today, how many pharmacies have earned this certification
19 from your organization?

11:16:56 20 **A.** 32.

21 **Q.** 32 around the country. Now, with VIPPS certification
22 they could represent themselves to be a VIPPS-certified
23 pharmacy, correct?

24 **A.** Correct.

11:17:10 25 **Q.** And but you don't have to be a VIPPS-certified

Catizone - Cross (By Ms. Rha)

1 pharmacy to advertise yourself as an Internet pharmacy,
2 correct?

3 **A.** No, you have to be certified to advertise on Google
4 and Microsoft.

11:17:25 5 **Q.** That's right. That's what I was going to point out.
6 You beat me to it. And the thing is, but if somebody were
7 to go on Google, if somebody were to go on -- what's the
8 other search engine? Microsoft?

9 **A.** Microsoft Bing.

11:17:38 10 **Q.** Right. But everybody uses Google, so if somebody were
11 to go on Google and type in like Internet pharmacy, the
12 Internet pharmacy that would be allowed to advertise
13 themselves on the Internet via Google search engine would
14 have to be certified by NABP --

11:17:56 15 **A.** Correct.

16 **Q.** -- through its VIPPS program, right?

17 **A.** Or e-Advertiser, correct.

18 **Q.** Right. I thought that was an interesting point. Now,
19 so you get your money -- when I say you, I know,

11:18:10 20 Mr. Catizone, you don't get compensated, but I'm talking
21 aside from the salary of \$450,000, but I'm talking about
22 your organization. NABP gets its money by, what's the word,
23 administering tests to people who want to become licensed
24 pharmacists; correct?

11:18:28 25 **A.** Developing and administering.

Catizone - Cross (By Ms. Rha)

1 **Q.** Right. You have to develop the test, and the test has
2 to be in accordance with things, right, that are pertinent
3 to the industry of pharmacy, I would think; right?

4 **A.** And it has to be a valid --

11:18:40 5 **Q.** It takes time and money to do that?

6 **A.** Yes.

7 **Q.** And then you also get money when a pharmacist in New
8 York wants to, I guess, move to Florida, move to Minnesota.
9 They would have to go through your organization to transfer
11:18:52 10 their license. Am I right?

11 **A.** Correct.

12 **Q.** And then you have the VIPPS program, and I guess you
13 could have some other program, but does NABP accept
14 contributions from pharmaceutical companies?

11:19:08 15 **A.** Only educational grants for educational programs, and
16 those are limited to \$5,000, and then nonrestricted grants
17 where the funding goes directly to the states and not to
18 NABP.

19 **Q.** So anything up to \$5,000, let's say a pharmaceutical
11:19:25 20 company that makes a particular drug, and I don't know any,
21 so whatever it may be, if they want to give your
22 organization money they could give you up to \$5,000, but
23 they would have to specify what type of educational program?
24 No?

11:19:42 25 **A.** No. When we hold the meeting we have various

Catizone - Cross (By Ms. Rha)

1 educational sessions, and then there are expenses for the
2 speakers and for the food, refreshment breaks. If somebody
3 wants to sponsor that they can submit a request and a grant
4 up to \$5,000. We decide what session they fund as well as
11:20:00 5 the content. They have no input.

6 We have accepted a million dollar grant from Purdue
7 Pharma to establish the prescription monitoring programs,
8 and every dollar of that million dollars is going to fund
9 the states for their cost to connect to an interstate
11:20:16 10 system. And all that is documented on our website, so you
11 can see how much is in the fund and how much each state has
12 been paid. That's the only grant of that nature, and it's
13 very transparent, and none of those funds are going to NABP
14 directly.

11:20:30 15 **Q.** And you used the word transparent because -- tell me
16 if you would agree with me -- that it's very important that
17 any money given by a pharmaceutical company composed of
18 agencies that regulate pharmacists and pharmacies, you
19 cannot have this conflict of interest, right?

11:20:52 20 **A.** Correct. And in fact --

21 **Q.** That's why --

22 **A.** -- our investment policy calls we cannot invest in
23 pharmaceutical companies or in pharmacies so we maintain
24 that objectivity.

11:21:01 25 **Q.** Because avoiding conflict of interest is very

Catizone - Cross (By Ms. Rha)

1 important to an organization that is made up of regulating
2 state agencies; correct, sir?

3 **A.** Correct.

4 **Q.** Now, in addition to pharmaceutical study grants, do
11:21:15 5 you get money from anywhere else then? Does the government
6 give you any grants?

7 **A.** The FDA has provided some grants for us to do studies
8 in regard to patient counseling, but those have not been
9 significant, maybe two or three that we received from the
11:21:31 10 FDA.

11 **Q.** Okay, so not anything from the government, some from
12 pharmaceutical companies. Do retail drug stores -- you've
13 heard of the term chain drug stores, correct?

14 **A.** Correct.

11:21:47 15 **Q.** Can you tell the jury what chain drug stores are?

16 **A.** It's generally a corporation that has -- some people
17 say more than four pharmacies, others might say 12 or 18, it
18 depends what definition. There's a central ownership,
19 central control, and they operate sometimes as a local
11:22:05 20 chain. Many of their sites are in one state or they can be
21 multi-state, like a Rite Aid or a Wal-Mart. Those are chain
22 pharmacies.

23 And chain pharmacies are also allowed to submit a
24 grant of up to \$5,000 to support educational programs at our
11:22:23 25 educational sessions, but not beyond that.

Catizone - Cross (By Ms. Rha)

1 **Q.** So when we say chain drug stores, that particular term
2 has a very definite meaning within your industry, correct?
3 Like the one you just described.

4 **A.** Yes.

11:22:36 5 **Q.** And if we were to give the jury examples of
6 pharmacists -- pharmacist -- no -- pharmacies that would fit
7 into that description, it would be stores like CVS?

8 **A.** Correct.

9 **Q.** Stores like Target?

11:22:51 10 **A.** Correct.

11 **Q.** Stores like Walgreens?

12 **A.** Correct.

13 **Q.** Rite Aid?

14 **A.** Yes.

11:22:55 15 **Q.** Eckerd's?

16 **A.** I'm not familiar with that.

17 **Q.** Oh, okay. All right. But anyway, stores like that,
18 right?

19 THE COURT: Ms. Rha, let's take about a
11:23:06 20 five-minute break. Let's take a short break.

21 THE CLERK: All rise.

22 (Recess had.)

23 THE COURT: Sir, you're still under oath.

24 THE WITNESS: Yes, sir.

11:35:19 25 THE COURT: Miss Rha.

Catizone - Cross (By Ms. Rha)

1 MS. RHA: Yes, sir.

2 **Q.** Mr. Catizone, before the break we talked about the
3 chain drug stores, right? And you said that you are allowed
4 to receive some grants or funding from them, but up to
11:35:47 5 \$5,000?

6 **A.** For the educational programs, yes.

7 **Q.** For the educational programs. So now we have with
8 respect to how NABP supports itself you have the sometimes
9 government grants, but not significant amount, and then you
11:36:04 10 have some money from some pharmaceutical companies, but for
11 limited purposes, for limited amount, and same thing goes
12 for the chain drug stores. Where else do you get your
13 funding?

14 **A.** From investments. Less than 1 percent come from
11:36:20 15 contributions from the pharmaceutical industry or the chain
16 drug stores. The balance is what I have explained prior,
17 the examination fees, the licensure fees, and the
18 accreditation fees.

19 **Q.** You did mention investments just now, right?

11:36:33 20 **A.** Yes.

21 **Q.** So NABP has investments?

22 **A.** Correct.

23 **Q.** Where do you hold your investments?

24 **A.** They're held in mutual funds, as well as in stocks and
11:36:42 25 bond accounts, different brokers.

Catizone - Cross (By Ms. Rha)

1 **Q.** And do you as the executive director of the
2 organization for the last 20 years, do you oversee where
3 these investments are placed so they're not being invested
4 in companies that could be in conflict with what your
11:36:58 5 organization stands for?

6 **A.** Yes.

7 **Q.** So making sure that they're not being invested in
8 drugs that are being developed or Internet pharmacies, or
9 other affiliations related to chain drug stores, et cetera?

11:37:10 10 **A.** Correct.

11 **Q.** Because again, once again, you would agree with me
12 that to achieve the goals that your organization has there
13 should not be any conflict of interest. For example, if you
14 are composed of state agencies that regulate pharmacies and
11:37:28 15 pharmacists then you should not be investing money or your
16 assets or receiving significant amount of money from the
17 very entities or people that you are regulating; correct?

18 **A.** Correct.

19 **Q.** Now, and we'll address that point again, but I just
11:37:44 20 want to finish this topic, and that is where NABP gets its
21 money from. How do you sustain yourself?

22 MR. FERAN: Objection.

23 **Q.** You as the executive director?

24 THE COURT: Ms. Rha, I'll allow you some
11:37:55 25 latitude, you have a right to explore those kinds of things,

Catizone - Cross (By Ms. Rha)

1 but I think you've probably covered most of that now.

2 MS. RHA: I have just maybe two more points to
3 make on this area, Judge, only because he said so yesterday
4 that they don't have to take his word for it. He's the
11:38:10 5 expert witness for the government --

6 THE COURT: Yes, but if you're asking some
7 open-ended questions, if you've got some that you want to
8 ask him, if you've got some information that there are
9 conflicts or may be conflicts, whatever, let's get on with
11:38:23 10 it.

11 MS. RHA: Sure, Judge, I will ask.

12 **Q.** The 2008 annual meeting that Mr. Darken asked you
13 about, that was held in May of 2008 in Baltimore, Maryland,
14 at the Marriott Hotel. Do you remember that meeting?

11:38:38 15 **A.** Yes.

16 **Q.** Obviously you as the executive director was involved
17 in the planning and the overseeing that particular meeting,
18 correct?

19 **A.** Correct.

11:38:47 20 **Q.** That was your organization's meeting, once-a-year
21 meeting, right?

22 **A.** Correct.

23 **Q.** And during that organization you also held continuing
24 pharmacy education, correct?

11:38:58 25 **A.** Correct.

Catizone - Cross (By Ms. Rha)

1 **Q.** And Mr. Darken asked you yesterday about the things
2 that were presented at the meeting, including there was a
3 session that was held titled case strategy, how to
4 investigate an Internet pharmacy. Do you remember that?

11:39:20 5 **A.** Yes.

6 **Q.** And do you remember you being asked about the things
7 that were taught during that particular session?

8 **A.** Correct.

9 **Q.** Right? And I'll get to that, but just going back to
11:39:29 10 the conflict issue that the Judge wanted me to address --

11 THE COURT: Yes. I want you to move along.

12 **Q.** Yes. Now, with respect to the conflict, now, when
13 that meeting began, and every time your organization holds
14 one of these annual meetings it's traditional to hold a
11:39:45 15 reception for the attendees, correct?

16 **A.** Correct.

17 **Q.** And I use that word traditional because it was used in
18 an article that quoted you, that there was a reception that
19 was held at the beginning of this meeting, and that
11:39:59 20 reception, I think you probably know where I'm going, that
21 reception was funded by the National Association of Chain
22 Drug Stores. Am I not right? I'm right?

23 **A.** Part of the cost was. The other part was our
24 foundation covered the other cost.

11:40:16 25 **Q.** Whether it be part or a total, let's tell the jury

Catizone - Cross (By Ms. Rha)

1 that that annual meeting that was held in 2008, the
2 reception was funded by the Chain Drugstore Association;
3 correct?

4 **A.** Yes.

11:40:29 5 **Q.** And then that reception cost \$21,000, correct?

6 **A.** Probably.

7 **Q.** And you were also interviewed by the *USA Today* when
8 they were looking into any potential conflict of interest
9 issues involving the National Association of Boards of
11:40:44 10 Pharmacy, the state agencies that make up the regulatory
11 bodies within each state; correct?

12 **A.** Correct.

13 **Q.** And you stated, you told the reporter, and you were
14 quoted in their article saying, "Yeah, in sum and substance,
11:40:57 15 yes, we should avoid conflict of interest, but it's
16 tradition."

17 **A.** Correct.

18 **Q.** Correct?

19 **A.** Correct.

11:41:02 20 **Q.** Now, you stated that NABP does not get involved in
21 lobbying, but NABP also has a subset called National
22 Association of Boards of Pharmacy Foundation. Am I not
23 right?

24 **A.** Correct.

11:41:19 25 **Q.** And if you looked up the website for NABP Foundation,

Catizone - Cross (By Ms. Rha)

1 it does say that it's involved in not only educational
2 activities, but regulatory initiatives, right?

3 **A.** Correct.

4 **Q.** And I put that in quotes, regulatory initiatives;
11:41:33 5 right?

6 **A.** Right.

7 **Q.** And regulatory initiatives really means, Mr. Catizone,
8 that you initiate regulations?

9 **A.** No.

11:41:41 10 **Q.** What's regulatory initiatives?

11 **A.** For example, right now I'm getting calls from
12 congressmen and senators in states with regard to the
13 meningitis issue and the people that have been killed by the
14 compounded product. They've asked us, is there more federal
11:41:54 15 regulation that's required? We want to initiate some
16 regulatory changes to the federal law.

17 The states are calling us saying, do we need to change
18 our state law, some new regulatory initiatives? So we
19 comment on those initiatives as they come up, but we don't
11:42:08 20 initiate them. We help the states and the federal
21 government deal with issues, like the meningitis issue, to
22 try and find out how to help patients and how to avoid this
23 in the future.

24 **Q.** So basically you're in touch, in communication with
11:42:24 25 agencies or government authorities or legislators who are

Catizone - Cross (By Ms. Rha)

1 interested in coming up with some sort of law, and they want
2 your comment, your feedback. When I said you, you or your
3 organization they you represent; right?

4 **A.** Correct.

11:42:38 5 **Q.** And you talked about VIPPS, you talked about not
6 getting compensated, you talked about how much money that
7 they pay you on an annual basis. Now, when I looked up the
8 expenses and revenues for your organization, which you say
9 is a 501(c)(3) charitable organization, I see that as of
11:43:05 10 December of 2010 your total revenue was \$25,572,604;
11 correct?

12 **A.** Correct.

13 **Q.** And then your expenses was \$18,366,192 as of December
14 of 2010; correct?

11:43:28 15 **A.** Correct.

16 **Q.** This is published; correct?

17 **A.** I said correct.

18 **Q.** And there was a net gain that year, as of December of
19 2010, of \$7,206,412; correct?

11:43:40 20 **A.** Correct.

21 **Q.** And as of end of December of 2010 your organization
22 held a total asset of \$60,112,796; right?

23 **A.** Correct.

24 **Q.** Now, I print this up, because every time you talked
11:43:58 25 about VIPPS -- and I don't represent a pharmacy in this

Catizone - Cross (By Ms. Rha)

1 trial, but I do want the jury to know -- you volunteered the
2 information that money loss, money loss, but to an
3 organization that has a total assets of \$60 million-plus two
4 years ago --

11:44:15 5 MR. FERAN: I object to this, Your Honor.

6 THE COURT: Okay.

7 MS. RHA: Withdrawn. Withdrawn. Let's just
8 move on. I'm speaking to myself. I'm going to move on.

9 **Q.** Now, 2008 annual meeting, right? This is my last
11:44:27 10 point with you. Mr. Darken asked you, there was a seminar
11 that was given entitled Case Strategy, How to Investigate an
12 Internet Pharmacy, and it was given by a Benjamin Gluck.
13 Correct?

14 **A.** Correct.

11:44:46 15 **Q.** And this is a seminar --

16 THE COURT: I'm just going clear about the
17 time today. I will have no opportunity -- how it works,
18 there will be no opportunity for me to stay beyond 12:30.
19 I'm just putting that on the record, and then we'll have to
11:45:03 20 deal with the time. If there's not enough, we'll have to
21 deal with it. All right?

22 MS. RHA: Thank you, Judge.

23 **Q.** Now, this seminar was put together by your
24 organization, correct?

11:45:17 25 **A.** Correct.

Catizone - Cross (By Ms. Rha)

1 Q. For its annual meeting, correct?

2 A. Correct.

3 Q. And in addition to that seminar, you held seminars on
4 other pertinent topics. For example, there was a seminar on
11:45:30 5 pedigree update, correct?

6 A. Correct.

7 Q. There was a seminar on Medicaid fraud, correct?

8 A. Correct.

9 Q. There was a seminar on compounding update, correct?

11:45:38 10 A. Correct.

11 Q. And you as the executive director was directly or
12 indirectly, and no pun intended, involved in selecting the
13 topics that would be appropriate to present to the members
14 who are coming to this very important annual meeting;
11:45:55 15 correct?

16 A. Correct.

17 Q. And you stated yesterday that you were there, right?

18 A. I was at the meeting, yes.

19 Q. And you were there during the seminar?

11:46:06 20 A. No. Because we had concurrent sessions running, so
21 some of the staff that are involved with compliance handle
22 that seminar, I went to the other sessions that dealt with
23 the board members --

24 Q. So you were the announcer of different seminars?

11:46:17 25 A. Yes.

Catizone - Cross (By Ms. Rha)

1 Q. Because you're the director, and you wanted to make
2 sure everything was running smoothly?

3 A. Correct.

4 Q. And you, with all your experience and presentation,
11:46:29 5 and testimonies and commentaries, and opinions and
6 feedbacks, would have to keep up with the trend in the
7 industry, so to speak; correct?

8 A. Correct.

9 Q. And you would also, I would think, would have to be
11:46:49 10 aware of the things that were being presented on behalf of
11 the National Association of Boards of Pharmacies; correct?

12 A. Correct.

13 Q. And you would also as the executive director, because
14 you've been doing this job for 20 years, so you would agree
11:47:03 15 with me, obviously your board members at your organization
16 seem to think you're doing a pretty good job; right? They
17 just gave you a raise of \$50,000 two years ago, right?

18 MR. FERAN: Judge, objection to this.

19 MS. RHA: Withdrawn.

11:47:16 20 Q. And so --

21 THE COURT: Now, Ms. Rha, you should have the
22 opportunity to ask questions, but you've got to -- let's not
23 go over old ground. If you've got some things that you
24 really want to ask him about that haven't been covered, go
11:47:38 25 ahead and do that directly; but we need to move on.

Catizone - Cross (By Ms. Rha)

1 MS. RHA: Yes, sir.

2 Q. So during this seminar or during this conference for
3 annual meeting, when you were going in and out of different
4 seminars and just overseeing things -- (pause.)

11:48:17 5 THE COURT: Can counsel approach the bench,
6 please, for a minute, everybody?

7 (Proceedings at side-bar:)

8 MS. LUTZKO: Your Honor, as I mentioned
9 yesterday, this witness has obligations, I did want to say
11:48:36 10 that this witness has obligations for the National Board of
11 Pharmacy that is going to put him out of pocket for two
12 weeks after today.

13 THE COURT: All right. Let me ask you this:
14 How much more do you have on redirect?

11:48:50 15 MR. FERAN: I'm going to bang through it in 15
16 minutes, Judge.

17 MS. LUTZKO: Half an hour.

18 MR. FERAN: Half an hour. I've got a lot to
19 cover. I'll go fast.

11:48:57 20 THE COURT: Do you have anything further?

21 MR. GORENCE: I don't know what Ed is going to
22 do, Your Honor. I have one question so far. I don't know.

23 THE COURT: How much more do you have?

24 MS. RHA: Five more minutes.

11:49:08 25 THE COURT: Five?

Catizone - Cross (By Ms. Rha)

1 MS. RHA: Depending on what he says. Five
2 minutes.

3 THE COURT: Let's move on.

4 (Proceedings had in open court:)

11:49:27 5 BY MS. RHA:

6 **Q.** Mr. Catizone, if you would take a look at what's on
7 the screen, do you remember seeing this PowerPoint
8 presentation, stated "States do not reflect the DEA's
9 purported consensus. 29 states, 58 percent, have medical
11:49:48 10 board policies addressing online prescribing. Some only say
11 things like Use of Internet does not change standards of
12 care, New York; most merely deem it unprofessional. None of
13 these say it is outside the course or an invalid
14 prescription." Do you remember hearing this?

11:50:03 15 **A.** I believe I testified to this earlier, and the answer
16 is yes.

17 **Q.** Now, at the same annual meeting, now, do you remember
18 seeing this PowerPoint presentation as part of that same
19 seminar?

11:50:17 20 **A.** Yes.

21 **Q.** The climate summary. And if you would take a look at
22 the highlighted portion especially, it says, "While some
23 sources" --

24 **A.** I've seen this document.

11:50:25 25 **Q.** I want to put it on the record. "While some sources,

Catizone - Cross (By Ms. Rha)

1 though certainly not all, deem online prescribing
2 unprofessional, the overwhelming majority do not treat it as
3 outside the usual course to the extent that it results in an
4 invalid prescription." Right? This was taught at the
5 2008 -- let me rephrase.

6 **A.** No, it wasn't taught. This was presented to be
7 objective --

8 **Q.** Mr. --

9 **A.** Wait. You asked the question. I'm answering the
10 question.

11 THE COURT: Wait. Wait --

12 **Q.** I did not ask that question --

13 THE COURT: You're both going to have to stop
14 talking. When I talk, that's the one rule you have to obey.
15 You have to stop.

16 Now, you're talking across the witness, and he got
17 back into it with you, but you're talking fast. And give
18 him a chance to answer the question, and you have to also
19 make sure that you say who showed it at the seminar, how it
20 was displayed at the seminar, some context for that.

21 MS. RHA: Okay, sir, I will.

22 THE COURT: So let's move on, but don't talk
23 across each other, and certainly when I'm talking, you
24 should stop right away.

25 MS. RHA: Yes, sir.

Catizone - Redirect (By Mr. Feran)

1 Mr. Catizone, I apologize. I will calm down.

2 **Q.** So this particular seminar given at the 2008 annual
3 meeting was given by a Benjamin Gluck; correct?

4 **A.** Correct.

11:51:36 5 **Q.** And he is not a board member or a member of the
6 National Association of Board of Pharmacy, right?

7 **A.** Correct.

8 **Q.** However, he was invited by your organization to come
9 and give this presentation; correct?

11:51:47 10 **A.** To present an objective view on both sides of the
11 issue, yes.

12 **Q.** Okay.

13 MS. RHA: Thank you, and no more questions.

14 THE COURT: Thank you, counsel. Mr. Feran?

11:52:13 15 REDIRECT EXAMINATION OF CARMEN CATIZONE

16 BY MR. FERAN:

17 **Q.** We're going to go in reverse order, Mr. Catizone.

18 Let's talk about the statements you just saw up on the
19 screen there. Can you explain what those statements are,
11:52:21 20 sir?

21 **A.** Sure. We have speakers at our meeting that present
22 all sides of the issue. That speaker was presenting
23 contrary views as to what the interpretations may be at a
24 recent annual meeting. We had a presentation on
11:52:34 25 pseudoephedrine, which is used to manufacture meth, and we

Catizone - Redirect (By Mr. Feran)

1 brought up proponents that said pseudoephedrine should not
2 be regulated, and those that said it should be regulated,
3 and they both provided facts on both sides saying why it
4 shouldn't and why it should.

11:52:47 5 We provide those types of programming so the boards
6 can have all the information, and then go back and make
7 objective decisions. That was the same in this case.
8 Individuals had different opinions and interpretations of
9 state and federal law. We give everybody a chance to be
11:53:00 10 heard and to have information presented.

11 **Q.** These comments did not reflect the view of your
12 organization. Is that correct, sir?

13 **A.** Correct, sir.

14 **Q.** Let's talk about when Miss Rha showed you the chart
11:53:10 15 and talked about materials that you've reviewed regarding
16 Dr. Sasaki. Do you remember those questions?

17 **A.** Yes.

18 **Q.** Focusing on he's not on the T III, he's not on the
19 controlled buys; correct?

11:53:20 20 **A.** Correct.

21 **Q.** Let's talk about all the materials you reviewed, sir.
22 Did you review -- in all the materials did you review
23 materials relating to Dr. Sasaki?

24 **A.** Yes. Dr. Sasaki was in other materials related to the
11:53:33 25 prescriptions, the processing of those prescriptions, and

Catizone - Redirect (By Mr. Feran)

1 Dr. Sasaki's efforts to involve other physicians to write
2 prescriptions on his behalf as part of this operation.

3 MR. MILANO: Objection, Your Honor. Can we
4 approach the bench?

11:53:51 5 THE COURT: You may.

6 (Proceedings at side-bar:)

7 MR. MILANO: Judge, my fear is I don't know
8 that this is accurate. My fear is the government is now
9 attempting to move down the Dr. Nelson line, because
11:54:15 10 questions were asked about specific things that he reviewed,
11 he is now saying he reviewed things about Dr. Sasaki
12 recruiting other physicians. And that gets us into the
13 statements which again Ms. Rha in no way opened the door to
14 these brand new opinions now on direct.

11:54:34 15 If that's not the case, if that's not what they're
16 doing, then I'm sorry.

17 MS. LUTZKO: Your Honor, a couple of points.
18 First of all, Ms. Rha elicited only some of the things he's
19 reviewed. She didn't explicitly make clear and tried to
11:54:46 20 create a false picture he hadn't reviewed other documents
21 that relate to Dr. Sasaki. We did not give him his
22 statement, we did not give him additional information he
23 had. What he had --

24 MR. MILANO: Then excuse me.

11:55:01 25 THE COURT: All right. There's no objection

Catizone - Redirect (By Mr. Feran)

1 now, right?

2 MR. MILANO: Well, no, if we're not in that
3 area where they're offering new opinions. I am not sure of
4 the basis he recruited other physicians --

11:55:09 5 MS. LUTZKO: He reviewed the indictment, he
6 reviewed all sorts of things. They're on the list.

7 THE COURT: Let me just say this. I'll give
8 limited latitude. She made a lot of the fact that he
9 reviewed everything that he ever saw, Dr. Sasaki anyway, and
11:55:25 10 I think it's fair, as long as you're talking about what he
11 reviewed.

12 MS. RHA: I said I listed the items that I was
13 questioning him about.

14 THE COURT: I know. The objection is
11:55:45 15 overruled. Let's move.

16 (Proceedings had in open court:)

17 **Q.** Okay. Mr. Catizone, we talked about Ms. Rha asked you
18 about T IIIs and controlled buys, correct?

19 **A.** Correct.

11:56:09 20 **Q.** Now, you reviewed materials that you listed other than
21 those materials, correct?

22 **A.** Correct.

23 **Q.** And these included the indictment and DEA-6s, correct?

24 **A.** Correct.

11:56:17 25 **Q.** As a result of your review of those materials, sir,

Catizone - Redirect (By Mr. Feran)

1 was Dr. Sasaki mentioned?

2 **A.** Yes.

3 **Q.** And what was his role in this organization, sir?

4 **A.** He worked with Dr. Cheslow in order to have approvals
11:56:29 5 of the orders that came over the Internet.

6 **Q.** Did you read pharmacy records related to Dr. Sasaki?

7 **A.** Yes. He was also involved in approving a number of
8 orders for those for the hydrocodone and other buys.

9 **Q.** Based on your training and experience, Mr. Catizone,
11:56:45 10 would you tell us about your thoughts on those approval
11 process?

12 **A.** In my opinion, I didn't believe there was a valid
13 patient-doctor relationship there, and those orders were
14 simply approved as part of this organization and part of
11:56:58 15 this operation.

16 **Q.** Why didn't you view this as a valid doctor-patient
17 relationship, sir?

18 **A.** Based on the information I reviewed, I didn't see any
19 consultation occur between the patients and the doctors. I
11:57:17 20 didn't see any follow up. And the number of orders that
21 were filled and the process for filling them also indicated
22 that the relationship didn't exist or wasn't created.

23 **Q.** We went into great detail about your compensation for
24 testimony and not being paid. Why do you agree to testify
11:57:32 25 here today, sir?

Catizone - Redirect (By Mr. Feran)

1 **A.** Because it's part of our mission to help the states.
2 When I first started at NABP we had an annual budget of less
3 than a million dollars, and we had seven staff. And because
4 we've been able to develop these programs and work with the
11:57:44 5 states, that's why the budget is where it's at today, and
6 because of the things we do for the states to try and help
7 the states.

8 **Q.** Let's move on, and we're going to talk about Mr.
9 Darken's questions to you. To start off, I'll talk about
11:57:57 10 medical records in a pharmacy. Correct? Do you remember
11 the first line of questions he asked you yesterday?

12 **A.** Yes, sir.

13 **Q.** Is it unusual that a pharmacist would have medical
14 records in his pharmacy during this time frame in the
11:58:10 15 conspiracy, sir?

16 **A.** Yes.

17 **Q.** Can you explain that, Mr. Catizone?

18 **A.** It came up in the questioning today, most pharmacies
19 don't have access to medical records, don't maintain medical
11:58:21 20 records. They're truly focused on the prescription
21 processing and the information they get from the
22 prescription.

23 **Q.** You talked about testifying, and it was gone through
24 in great length on certain dates you testified for the
11:58:37 25 government in various trials. Do you remember that line of

Catizone - Redirect (By Mr. Feran)

1 questioning?

2 **A.** Yes, sir.

3 **Q.** You also stated you testified in administrative
4 hearings. Is that correct, sir?

11:58:44 5 **A.** Yes, sir.

6 **Q.** And how many times was that?

7 **A.** Probably about half a dozen or so, sir.

8 **Q.** And what context was that, Mr. Catizone?

9 **A.** In terms of the administrative hearings on behalf of
11:58:57 10 the government, they were for DEA registration revokes,
11 revocations.

12 On the other side, in regards to pharmacists, I've
13 testified in about 20 administrative hearings where we have
14 felt that the board acted inappropriately against the
11:59:10 15 pharmacist, and so we've testified on the pharmacist's
16 behalf and asked the Board of Pharmacy to reconsider their
17 action or reinstate their license, or to make an exception
18 for the pharmacist because of the board acting out of its
19 course of duty, or perhaps in some other way that we didn't
11:59:26 20 think was fair to the pharmacist, or in conformance with
21 what the laws and regulations were in that state.

22 **Q.** So you've testified for accused pharmacists, sir?

23 **A.** Yes.

24 **Q.** Against a charging agency?

11:59:36 25 **A.** Yes.

Catizone - Redirect (By Mr. Feran)

1 **Q.** Let's talk about, Mr. Darken talked about red flags.
2 Do you remember that line of questioning?

3 **A.** Yes, sir.

4 **Q.** And he mentioned in and of itself is this sufficient
11:59:47 5 where a doctor is in one state and the pharmacist and the
6 patient is in another state. Do you remember that?

7 **A.** Yes, sir.

8 **Q.** Are red flags, Mr. Catizone, are they viewed in
9 isolation?

11:59:59 10 **A.** Each of the red flags taken by themselves would be
11 something the pharmacist would investigate, but wouldn't
12 necessarily say this was an invalid relationship. When you
13 look at the situation, all of those red flags were present,
14 so it wasn't one or two. All the red flags were present.
12:00:16 15 So if you look at the situation in total, those red flags
16 all add up to the situation, and the opinion that talked
17 about not having a valid prescription and not dispensing
18 these prescriptions appropriately.

19 **Q.** Mr. Catizone, you previously ascribed the legal
12:00:32 20 obligations or requirements a pharmacist must do to insure a
21 prescription is valid. Do you remember talking about that,
22 sir?

23 **A.** Yes, sir.

24 **Q.** Are these requirements uniform throughout the United
12:00:42 25 States?

Catizone - Redirect (By Mr. Feran)

1 **A.** Yes, they are. And they apply for Internet pharmacies
2 as well as the additional brick and mortars, and that's why
3 you didn't have a lot of states acting early on for special
4 Internet regulation. The requirements, the standards
12:00:55 5 already existed. The states were trying ways to implement
6 them and deal with a whole new entity, because the Internet
7 isn't really much more than a telephone in communicating,
8 but the states needed some new tools to deal with these
9 pharmacies that were operating in multiple states.

12:01:10 10 **Q.** Would you go to 976 in front of you, sir? I know you
11 have a lot of documents. This is the DEA memo. Is that in
12 front of you?

13 **A.** Yes.

14 **Q.** Go to page 1 on that, sir. Now, the date on this is
12:01:21 15 2001, correct?

16 **A.** Correct.

17 **Q.** Is this a guidance document?

18 **A.** Yes.

19 **Q.** What's a guidance document? Can you explain this?

12:01:28 20 **A.** The DEA has responsibility for the Controlled
21 Substances Act. They issue regulations. They also issue
22 guidance documents. The guidance document has the same
23 weight and bearing as regulation, because the DEA will use
24 this in issues and matters to prosecute pharmacies or
12:01:44 25 pharmacists or doctors, based upon the guidance document,

Catizone - Redirect (By Mr. Feran)

1 which is their interpretation of the law and the statutes.

2 **Q.** Mr. Catizone, is the regular prescribing day after day
3 of hydrocodone for people residing in multiple states
4 something that should cause a pharmacist to question these
12:02:01 5 prescriptions?

6 **A.** Yes.

7 **Q.** Can you explain that, sir?

8 **A.** Prescriptions for patients in multiple states from
9 doctors that may be in different states than the patients,
12:02:08 10 and the doctors and patients that are in different states of
11 the pharmacist, would raise red flags. Generally the
12 pharmacist is familiar with the doctors that they're going
13 to dispense prescriptions for, the patients they're
14 dispensing for; without that familiarity the pharmacist has
12:02:24 15 to do his due diligence or her due diligence, and verify
16 everything occurring is valid.

17 **Q.** Sir, is it usual for a Florida pharmacist to regularly
18 fill prescriptions for a Puerto Rican doctor day after day?

19 **A.** For patients that are not located, again, within that
12:02:39 20 pharmacy's area that the pharmacist is familiar with, and
21 not knowing the doctor, a validating doctor, the answer
22 would be it's unusual.

23 **Q.** We went into a series, and I believe you have them, of
24 NABP, Mr. Darken went into it, Minnesota news, North
12:03:01 25 Carolina, Minnesota? Do you see those, sir? I'm referring

Catizone - Redirect (By Mr. Feran)

1 to VD-3, VD-9, VD-5. Do you see those, sir?

2 **A.** Yes, I do.

3 **Q.** Do you have those in front of you, sir?

4 **A.** Yes, I do.

12:03:12 5 **Q.** Are the statutes the only thing that establish a
6 doctor-pharmacist requirements for practice?

7 **A.** No. It's based upon the federal law that we talked
8 about earlier, where the basis says it must be a valid
9 prescription. Then it occurs in state statutes and
12:03:31 10 regulations, where it may be specifically cited, or it's
11 based upon the standards of practice that exist for that
12 particular patient, that particular profession. As.

13 An example, I think one of the examples given was
14 Louisiana, that it didn't pass in 2007. However, the
12:03:45 15 research that I did last night, Louisiana Board Reg 2515 in
16 1989 talked specifically about questionnaires, the number of
17 prescriptions, and a matter of authorization electronically
18 for prescriptions.

19 So the states had things in place at this time period
12:04:04 20 and beyond. What was presented today were simply updates or
21 moving things from regulation to statute so that they would
22 be stiffer penalties for those infractions, or that that
23 message would be even clearer for those individuals involved
24 in that activity.

12:04:18 25 **Q.** And all of these things that Mr. Darken showed you,

Catizone - Redirect (By Mr. Feran)

1 what I'm referring to, the Minnesota, Montana, North
2 Carolina, and on we go, does that change your testimony
3 regarding the requirements for pharmacists to distribute a
4 controlled substance in the usual course of business?

12:04:39

5 **A.** No.

6 **Q.** Can you tell us, can you explain that, sir?

7 **A.** As I mentioned, the standard already existed, whether
8 it was an Internet pharmacy or traditional brick and mortar
9 pharmacy. The difference with an Internet pharmacy was
10 these activities were occurring in cyberspace in terms of
11 the transfer of the prescriptions, patient information, so
12 there had to be some new regulations regarding how to
13 protect that information. There was also questions of
14 identity theft, how to protect for that.

12:05:04

15 So the new regulations focused more on how do we
16 regulate this new entity; not the standard of care, not what
17 defined valid prescription. That's existed, it existed
18 because of the state and federal laws and standards of
19 practice. Internet pharmacies didn't change that.

12:05:20

20 **Q.** Did the requirements for a pharmacist which you talked
21 about yesterday, criteria that the pharmacist must use prior
22 to dispensing a prescription, did any of this change that,
23 sir?

24 **A.** No, it didn't.

12:05:30

25 **Q.** Did the corresponding responsibility change, sir?

Catizone - Redirect (By Mr. Feran)

1 **A.** No, it didn't.

2 **Q.** Did the nature of a physician-patient relationship
3 change, sir?

4 **A.** No, it didn't. Just as a note, too, I did have a
12:05:45 5 chance to review the case the attorney asked me to review,
6 so whenever it's appropriate, I'd be glad to answer his
7 question on that, as well.

8 **Q.** Let's talk about that, about the various laws you
9 reviewed, sir. Can you talk about that?

12:05:57 10 **A.** The court case that I reviewed?

11 **Q.** Oh, no. Strike that. You stated that you looked at
12 some various laws last night?

13 **A.** Correct. I looked at the 20 states that I mentioned
14 earlier where these requirements were in place around 2001,
12:06:13 15 2005, and I actually found there were 22 states at that time
16 that had specific Internet requirements or dealt
17 specifically with questionnaires, required a face-to-face
18 consultation, or required our VIPPS program, or deferred to
19 NABP for standards we would develop in regard to Internet
12:06:33 20 practice.

21 **Q.** Mr. Catizone, we talked about in 2004 most states had
22 not passed laws regarding Internet pharmacies.

23 **A.** Yes.

24 **Q.** Can you explain why?

12:06:43 25 **A.** They didn't need to.

Catizone - Redirect (By Mr. Feran)

1 Q. Why didn't they need to?

2 A. The standards were already there whether it was
3 Internet or regular practice. The states began addressing
4 some of the other issues that were emerging based upon
12:06:54 5 Internet practice with some new regulations and new
6 requirements, and then used that to further strengthen the
7 existing standards by specifically mentioning them or
8 mentioning them again.

9 Q. Mr. Catizone, have Internet pharmacies ever been held
12:07:06 10 to a different standard than brick and mortar pharmacies?

11 A. Not based upon my experience.

12 Q. Can you explain that, sir?

13 A. Again, it is the same standards, same standards of
14 care, same standards for validating prescriptions and
12:07:19 15 relationships.

16 Q. VD-4, if you can pull that up, sir. Do you see it's
17 talking about the North Carolina one?

18 A. Okay.

19 Q. And you were asked some questions on VD-4 about
12:07:41 20 electronic signatures, correct?

21 A. Correct.

22 Q. And when was the applicable time period relating
23 to -- can you explain electronic signatures and the time
24 period relating to them?

12:07:51 25 A. I will explain it in the context of this document. It

Catizone - Redirect (By Mr. Feran)

1 really doesn't matter what North Carolina passed.

2 **Q.** Why doesn't it matter, sir? Can you explain that, why
3 it doesn't matter what North Carolina passed?

4 **A.** What they've said here is electronic signatures were
12:08:04 5 possible, but however, the DEA had a requirement that said
6 you could not engage in this activity, electronic signatures
7 weren't acceptable.

8 To give another example, the DEA says that medical
9 marijuana cannot be dispensed, it's illegal, but a number of
12:08:20 10 states have passed laws saying that you can have medical
11 marijuana, you can sell medical marijuana. Those pharmacies
12 or those dispensaries are still in violation of federal law,
13 and at any time the DEA could go in and arrest those
14 individuals for using or selling medical marijuana.

12:08:37 15 The same situation existed here. Even though North
16 Carolina said you could do it in North Carolina, the federal
17 law which was more stringent still stood, and if the DEA
18 wanted to go in and prosecute any of those pharmacies or
19 doctors using electronic signatures, they still had the
12:08:51 20 authority to do so regardless of state law.

21 **Q.** And the federal law in effect at this time said what,
22 sir?

23 **A.** That Internet signatures and electronic signatures
24 were not allowed; fax and oral prescriptions only.

12:09:04 25 **Q.** Are they allowed now?

Catizone - Redirect (By Mr. Feran)

1 **A.** Yes. Electronic prescribing has just been approved by
2 the DEA.

3 **Q.** And when was that, sir?

4 **A.** Within the last year or so for controlled substances.

12:09:13 5 **Q.** It was after 2009?

6 **A.** Correct.

7 **Q.** Let's talk about you have Government's Exhibit Number
8 VD-8 in front of you, and this is the letter. Defense
9 Exhibit VD-8. Do you have that in front of you?

12:09:39 10 **A.** Yes, sir, I do.

11 **Q.** And this is a letter dated August 24 of 2011. Is that
12 correct, sir?

13 **A.** Correct.

14 **Q.** And in this letter you're talking about Schedule II
15 controlled substances, correct?

12:09:51 15

16 **A.** Correct.

17 **Q.** And this letter references corresponding
18 responsibilities and references to federal and state law,
19 correct?

12:10:02 20 **A.** Correct.

21 **Q.** And the last line of paragraph 2, "consequently," can
22 you read that, Mr. Catizone?

23 **A.** Consequently, DEA expects that when information is
24 missing from or needs to be changed on a Schedule II
12:10:16 25 controlled substance prescription pharmacists use their

Catizone - Redirect (By Mr. Feran)

1 professional judgment and knowledge of state and federal
2 laws and policies to decide whether it's appropriate to make
3 changes to that prescription.

4 **Q.** Can you explain what that means, sir?

12:10:26 5 **A.** It's fairly clear, even though there's the ability for
6 pharmacists to use their professional judgment, it still has
7 to be in compliance with state and federal laws.

8 **Q.** Let's talk about Mr. Darken talked about DEA knows if
9 you're distributing 100 controls and 100 noncontrols,
12:10:43 10 correct? Do you remember that line of questioning?

11 **A.** Yes.

12 **Q.** DEA also knows if you're distributing 100 controls and
13 zero noncontrols; is that correct, sir?

14 **A.** They know how many controls.

12:10:54 15 **Q.** By the reporting requirements?

16 **A.** They just know about controlled substances.

17 **Q.** All right. We talked about prescriptions with
18 insurance, and you said 97 percent of prescriptions are
19 filled with insurance; correct, sir?

12:11:09 20 **A.** Yes.

21 **Q.** We talked about fill fees. Remember, Mr. Darken asked
22 you about fill fees?

23 **A.** Yes, sir.

24 **Q.** Is a pharmacist in your training and experience,
12:11:24 25 Mr. Catizone, does a pharmacist charge different fill fees

Catizone - Redirect (By Mr. Feran)

1 based upon whether a person has insurance or no insurance?

2 **A.** I'm not -- I can't comment on that one.

3 **Q.** You stated that you worked at Osco's between '78 and
4 '85, sir?

12:11:42 5 **A.** Correct, as a full-time --

6 **Q.** As a full-time pharmacist?

7 **A.** As a technician, and a full-time pharmacist from '83
8 to '85.

9 **Q.** And during that time period you had mechanisms in
12:11:51 10 place to make sure scripts did not go to the same address?

11 **A.** Yes.

12 **Q.** This was before the computer age, so to speak,
13 correct?

14 **A.** Correct.

12:11:58 15 **Q.** Back in the late '70s and mid-'80s?

16 **A.** Correct.

17 **Q.** And you were able to insure during that time period
18 without the aid of computers that scripts didn't go to the
19 same address?

12:12:07 20 **A.** We worked hard to make sure it didn't happen.

21 **Q.** Let's talk about there was questions, sir, between you
22 and Mr. Darken about this case. He stated this case does
23 not involve the distribution of drugs solely based on
24 questionnaires. Do you remember that?

12:12:27 25 **A.** Yes.

Catizone - Redirect (By Mr. Feran)

1 Q. And you would disagree with him on that. Do you
2 remember that?

3 A. Yes.

4 Q. And can you explain what you're talking about there,
12:12:33 5 sir?

6 A. I think the context there was that the medical records
7 that were being used were legitimate medical records, and
8 that's where the disagreement came in. Medical records
9 provided by the patients instead of by a doctor or other
12:12:45 10 health care professional that's conducted that examination
11 and completed that medical record wouldn't constitute a
12 medical record, in my opinion, and therefore we're dealing
13 with a situation where medical records don't exist, and
14 we're dealing with just questionnaires.

12:12:59 15 Q. You looked at the controlled buys in this case, didn't
16 you, Mr. Catizone?

17 A. Yes.

18 Q. And in some of those controlled buys were controlled
19 substances distributed based solely on a questionnaire?

12:13:13 20 A. Yes.

21 Q. And can you tell us your opinion on this, sir?

22 A. They were distributed based on the questionnaire
23 without a valid relationship, without any other
24 documentation.

12:13:23 25 Q. And what is your opinion on this type of activity,

Catizone - Redirect (By Mr. Feran)

1 sir?

2 **A.** It's in violation of state and federal laws and
3 standards of practice.

4 **Q.** Do you have Defendant's Exhibit VD-7 in front of you,
12:13:34 5 sir? If you would look for that.

6 **A.** Sure.

7 **Q.** Let me know when you have it.

8 **A.** Go ahead, I have it.

9 **Q.** You have it in front of you?

12:13:43 10 **A.** Yes.

11 **Q.** And this is the Florida law, for the record,
12 64B16-27.813; correct?

13 **A.** Yes, sir.

14 **Q.** And it talks about standards of practice dispensing
12:13:56 15 controlled substances and treatment of pain?

16 **A.** Yes.

17 **Q.** It talks about the legitimacy of a prescription,
18 correct?

19 **A.** Yes, sir.

12:14:01 20 **Q.** And in subcategory 2 there are five things that are
21 listed for a pharmacist to determine whether or not a
22 prescription is legitimate. Is that correct, sir?

23 **A.** Yes.

24 **Q.** All right. Now, B is what?

12:14:20 25 **A.** B is only controlled substance medications are

Catizone - Redirect (By Mr. Feran)

1 prescribed for a patient.

2 **Q.** Did that exist in this case, sir?

3 **A.** It existed, yes, it did.

4 **Q.** And what was the controlled substance?

12:14:31 5 **A.** Primarily hydrocodone.

6 **Q.** All right. We have E. Can you read that, sir?

7 **A.** Patients always pay cash and always insist on brand
8 name product.

9 **Q.** Did that exist in this case, sir?

12:14:48 10 **A.** The cash part did, yes.

11 **Q.** D. Can you talk about that, sir?

12 **A.** Same or similar controlled substance medications
13 prescribed by two or more prescribers at the same time. I
14 think we talked about some examples of that, where patients
15 were getting the same prescriptions from the same
16 prescribers and sometimes on the same date.

17 **Q.** If -- and it says if any of the two criteria -- if any
18 of the criteria is met, which it does here, it says the
19 pharmacist shall do certain things. Is that correct?

12:15:31 20 **A.** Correct.

21 **Q.** Mr. Catizone, in your practice, if you were confronted
22 with a situation like this, what would you do?

23 **A.** I would immediately contact the doctor to determine if
24 it was a valid prescription. If it wasn't a valid
12:15:43 25 prescription I wouldn't dispense it, and I would notify

Catizone - Redirect (By Mr. Feran)

1 authorities if there was a problem here occurring, probably
2 some fraud or diversion.

3 **Q.** During questions, sir, by Mr. Darken, he talked about
4 IDs in this case. Do you remember that line of questions?

12:16:04

5 **A.** Yes.

6 **Q.** Did you know that the government used fake IDs to
7 obtain drugs in this case?

8 **A.** Yes.

12:16:13

9 **Q.** If you were presented with an ID that you had
10 questions about, what would you do, sir?

11 **A.** Again, it is the responsibility to question and
12 investigate that ID to the best ability of the pharmacist.

13 **Q.** We talked about the Internet, and it started in 1999,
14 and it continues today. Is that correct, sir?

12:16:29

15 **A.** Yes.

16 **Q.** Has the Internet changed throughout the years?

17 **A.** Yes.

18 **Q.** Did the practice of the online pharmacies change
19 throughout the years?

12:16:36

20 **A.** Yes.

21 **Q.** Did the practice of rogue pharmacies change throughout
22 the years?

23 **A.** Yes.

24 **Q.** Can you tell us how they changed over time, sir?

12:16:43

25 **A.** Sure. The first wave of the Internet were companies

Catizone - Redirect (By Mr. Feran)

1 like amazon.com that thought you could sell prescriptions
2 without -- medications without a prescription like you could
3 sell a CD or a book. As soon as those entities were made
4 aware that that was illegal we moved into a different phase,
12:17:00 5 where a lot of senior citizens who couldn't afford
6 medication went to the Internet to try and buy products from
7 Canada and outside of the U.S. And it became an issue with
8 states where states were passing or allowing this to occur,
9 in direct violation of their own laws and federal laws.

12:17:15 10 With the implementation of the Medicare drug plan,
11 that went away, and many seniors until they get into the
12 doughnut hole are able to get their medications now through
13 a Medicare plan, and they're more affordable.

14 The latest phase has been for the deliberate
12:17:30 15 acquisition of drugs without a prescription, and some of the
16 processes that were -- an example in this case -- for people
17 to just buy prescription medications without prescriptions
18 and to use the Internet to get drugs that they couldn't get
19 through any legitimate process or legitimate evaluation.

12:17:46 20 THE COURT: Mr. Feran?

21 MR. FERAN: Yes, Your Honor.

22 THE COURT: To be fair, I would be thinking
23 three or four minutes.

24 MR. FERAN: I'm going to have it wrapped up.
12:17:54 25 Thank you, Judge, just a couple more questions.

Catizone - Redirect (By Mr. Feran)

1 **Q.** Let's move on, Mr. Catizone, and we'll finish up, sir.
2 You talked about legitimate telemedicine. Do you remember
3 talking about that?

4 **A.** Yes, sir.

12:18:05 5 **Q.** What is legitimate telemedicine?

6 **A.** That's where the patient has been seen by a doctor and
7 there's been a physical evaluation, and then there's a
8 relationship between that patient, the doctor, and the
9 covering doctor or referral doctor, where both doctors are
12:18:21 10 fully informed about the patient, their tests, their
11 diagnosis, and information. Even though that second doctor
12 may not have conducted the physical evaluation there is that
13 communication and collaboration between all three parties,
14 the two doctors and the patient.

12:18:35 15 **Q.** Mr. Catizone, based on your training and experience,
16 did legitimate telemedicine occur in this case?

17 **A.** No.

18 **Q.** Why not?

19 **A.** Again, it was no valid relationship. The
12:18:45 20 consultations weren't conducted with the doctors in many
21 cases, and the information reviewed, the medical records
22 that they claim are medical records, those evaluations
23 weren't conducted by a doctor or health care professional.
24 Information was self-reported, it wasn't reliable. The
12:19:00 25 doctors didn't look at that information, didn't the conduct

Catizone - Redirect (By Mr. Feran)

1 the examinations, didn't have a relationship with a patient.

2 **Q.** And lastly, Mr. Gorence talked about pharmacists being
3 fooled and how they would have no way of knowing the scripts
4 were altered. Do you remember that line of questioning by
12:19:16 5 Mr. Gorence, sir?

6 **A.** Yes, sir.

7 **Q.** If you're a pharmacist, what would you look at to
8 determine a valid script?

9 **A.** All the elements we talked about before, but that is
12:19:25 10 an issue that pharmacists are especially trained to deal
11 with. The state boards and the DEA always sent out
12 information about how to deal with these situations, how to
13 know if there's a doctor involved or a patient that may be
14 trying to dupe the pharmacist. So it's part of the training
12:19:39 15 and education that a pharmacist receives, and what's the
16 responsibility to look at the various red flags that we've
17 talked about earlier in this case.

18 **Q.** And lastly, sir, did you review the numbers of the
19 hydrocodone scripts that went out in this case?

12:19:54 20 **MR. DARKEN:** Your Honor, object. Same
21 argument. I think you sustained it yesterday.

22 **THE COURT:** Did I?

23 **MR. DARKEN:** Beyond the scope of the report.
24 Rule 16. Same objection.

12:20:10 25 **THE COURT:** I'm not for sure.

Catizone - Redirect (By Mr. Feran)

1 MR. GORENCE: Your Honor, I would join. And
2 the problem is we're getting into this, then he's going to
3 come back in a couple weeks, because it is a whole new area
4 we never had notice.

12:20:21 5 MR. FERAN: Your Honor, let me --

6 **Q.** Mr. Catizone, did you review the distribution pattern
7 of hydrocodone in this case?

8 **A.** Yes.

9 MR. DARKEN: Same objection. Rule 16, beyond
12:20:34 10 the scope.

11 MR. FERAN: Judge, he's a pharmacist. It's
12 not beyond the scope.

13 MR. DARKEN: It's beyond the scope.

14 MR. FERAN: It is not beyond the scope.

12:20:41 15 MR. DARKEN: It is beyond the scope of the
16 report we were given as an expert under Rule 16, Your Honor.

17 MR. FERAN: Judge, he's a pharmacist. He's
18 talking about pharmacy distribution patterns.

19 MR. DARKEN: If we had gotten the
12:20:52 20 information --

21 THE COURT: Just a minute.

22 MR. DARKEN: -- that would be fine.

23 THE COURT: Let me see the report again.

24 (Proceedings at side-bar:)

12:21:40 25 THE COURT: Okay. I have the report. So

Catizone - Redirect (By Mr. Feran)

1 Mr. Feran, you want to ask him -- what's the question?

2 MR. FERAN: I'm not asking him numbers, I'm
3 asking day after day the pharmacists are prescribing the
4 same prescription over and over again, is that a cause for
12:22:09 5 concern.

6 MS. LUTZKO: To people located in different
7 states.

8 MR. DARKEN: If that's the only question then
9 I don't have an objection. I thought you were going into
12:22:16 10 the volume, the numbers.

11 MR. FERAN: No, I'm talking about the day
12 after day repetitive nature of it.

13 THE COURT: Let me be clear. His report
14 supports a question of that type, right?

12:22:26 15 MR. DARKEN: I thought we were going way
16 beyond that.

17 (Proceedings had in open court:)

18 BY MR. FERAN:

19 **Q.** Lastly, Mr. Catizone, if day after day after day a
12:22:49 20 doctor is prescribing hydrocodone to patients located in
21 different states, is that a problem?

22 **A.** It would be a red flag, yes.

23 **Q.** And if it happens 5, 10, 15 or 20 times, is that
24 indicative of anything?

12:23:00 25 **A.** There's a pattern there that's probably not patient

Catizone - Recross (By Mr. Darken)

1 care, probably some sort of drug scheme, drug trafficking,
2 some other reasons for distribution.

3 MR. FERAN: Judge, thank you. I have no
4 further questions.

12:23:11 5 THE COURT: All right.

6 RE CROSS-EXAMINATION OF CARMEN CATIZONE

7 BY MR. DARKEN:

8 **Q.** Sir, we're going to try to do this pretty quick. If I
9 go too fast, let me know.

12:23:23 10 Mr. Feran asked you how many times you've testified
11 for accused pharmacists. Do you remember that?

12 **A.** Yes, sir.

13 **Q.** None of those were criminal cases, right?

14 **A.** No, sir.

12:23:35 15 **Q.** Mr. Feran asked you if it was unusual for a Florida
16 pharmacist to fill scripts from a Puerto Rican doctor. Do
17 you remember that?

18 **A.** Yes, sir.

19 **Q.** You said it was unusual. Do you remember that?

12:23:45 20 **A.** Yes, sir.

21 **Q.** Are you aware that the largest population of Puerto
22 Ricans in the United States outside of New York City is in
23 the Kissimmee area outside Orlando? Are you aware of that?

24 **A.** No, sir.

12:23:55 25 **Q.** Mr. Feran asked you about a Louisiana statute or

Catizone - Recross (By Mr. Darken)

1 pharmacy board regulation from 1989, 21-1-5. Do you
2 remember that?

3 **A.** Yes, sir.

4 **Q.** That was a questionnaire-based prohibition, correct?

12:24:14 5 **A.** Yes, sir. I think it was the board regulation was
6 25-1-5 that I reviewed yesterday, sir.

7 **Q.** Okay. Now, you said that you reviewed some material
8 last night, and you found 22 states between 2000 and 2005;
9 is that correct?

12:24:34 10 **A.** 2000 and 2007, sir.

11 **Q.** 2000 and 2007, okay. How many of those were -- you
12 talked about VIPPS and face-to-face together. How many of
13 those 22 states specifically prohibited or specifically
14 required face-to-face interaction of the 22?

12:24:55 15 **A.** Between that time period all 22 did, sir.

16 **Q.** All right. Now, you testified in response to
17 Mr. Feran, he asked you some questions about electronic
18 signatures. Do you remember that?

19 **A.** Yes, sir.

12:25:20 20 **Q.** And then you brought up this medical marijuana
21 analogy, and then you said that just because some state may
22 allow somebody to dispense medical marijuana, it's still a
23 federal crime. Do you remember that?

24 **A.** Yes, sir.

12:25:33 25 **Q.** And you said you can be arrested for that, right?

Catizone - Recross (By Mr. Darken)

1 **A.** Prosecuted by the DEA, yes.

2 **Q.** Right. Electronic signatures is an administrative
3 requirement, right?

4 **A.** Yes, sir.

12:25:42 5 **Q.** You don't get arrested for not complying with that?

6 **A.** No, sir.

7 **Q.** Correct? So that was a little bit of a -- not an
8 exact analogy there, correct?

9 **A.** It was just a misspeak of terms. I apologize.

12:25:55 10 **Q.** Okay. You weren't trying to tell the jury that if you
11 don't do electronic signatures correct the DEA comes and
12 takes you off to jail, right?

13 **A.** No, sir, I wasn't.

14 **Q.** Okay. And what we're talking about there is the
12:26:08 15 difference between a fax signature and an e-mail signature,
16 correct?

17 **A.** Correct, sir.

18 **Q.** All right. So DEA up until a year ago was still in
19 the fax era, correct?

12:26:23 20 **A.** Yes, sir.

21 **Q.** All right. Mr. Feran asked you about the 100 controls
22 versus 100 noncontrolled. Do you remember that?

23 **A.** Yes, sir.

24 **Q.** And he asked you a question, and you said that DEA has
12:26:37 25 no ability to track noncontrols, right?

Catizone - Recross (By Mr. Darken)

1 **A.** Yes, sir.

2 **Q.** Okay. You can't fool DEA about noncontrols because
3 they don't keep track of noncontrols, right?

4 **A.** Typically, no, sir.

12:26:49 5 **Q.** You said that medical records don't -- you don't
6 believe that medical records existed in this case because
7 they were submitted by patients, correct?

8 **A.** Yes, sir.

9 **Q.** All right. So if I have a cardiologist and he
12:27:14 10 retires, he's going to go out of practice, and I go to my
11 cardiologist and I pick up my records, and then I go to my
12 new cardiologist and I give him my records, under your
13 scenario those medical records don't exist. Is that
14 correct?

12:27:26 15 **A.** I said they wouldn't be used as a basis for a valid
16 prescription. Your new cardiologist would probably conduct
17 an examination on you to substantiate the records he
18 received and start a new patient profile on you, sir.

19 **Q.** Didn't you say those medical records don't exist?

12:27:42 20 **A.** In my opinion they weren't -- I wouldn't consider them
21 medical records.

22 **Q.** I've got one thing to show you, and then I'm done.

23 Can I have the ELMO? I'm not a math genius, so I did the

24 numbers myself, and I can show you. If you have a phone you

12:28:34 25 can check it, or I can check it. How do I zoom? There. So

Catizone - Recross (By Mr. Darken)

1 we have 50 states in the country, right?

2 **A.** Correct.

3 **Q.** And we have the District of Columbia, that's a member
4 of your organization, Commonwealth of Puerto Rico is a
12:28:46 5 member of your organization. Guam you said is a member of
6 your organization, and you said the U.S. Virgin Islands is a
7 member of your organization?

8 **A.** Correct.

9 **Q.** Didn't you testify to that in response to Mr. Feran?

12:28:56 10 **A.** Correct.

11 **Q.** All right. So that's 54 jurisdictions. And you said
12 last night you found that 22 of them had some sort of laws
13 or standards or pharmacy board rules or something about
14 face-to-face between 2000 and 2007, correct?

12:29:13 15 **A.** Correct.

16 **Q.** Now, 22 over 54 is 40.7 percent; correct?

17 **A.** I'll trust your math. Yes.

18 **Q.** Well, don't trust me. Do you want my phone?

19 **A.** No.

12:29:24 20 **Q.** Okay. Do you want to do the math?

21 **A.** Yes. Yes. 40.7.

22 **Q.** And that's less than half. 40.7 percent is less than
23 half. You agree with that?

24 **A.** I agree.

12:29:37 25 **Q.** And 54 minus 22 is 32 jurisdictions that did not have

Catizone - Recross (By Mr. Darken)

1 what you testified existed between 2000 and 2007, correct?

2 **A.** No. What I said is that the standards already
3 existed, these states took additional action to codify that
4 further, so my opinion and my statement would be the
12:30:00 5 requirement existed in all of the states just as the DEA
6 issued in their 2001 letter that the states have this in
7 place. That would be my opinion, sir.

8 **Q.** Let well ask you this. You went back last night, and
9 you found 22 states that you testified had face-to-face
12:30:16 10 requirements of some sort between 2000 and 2007, correct?

11 **A.** Yes, sir.

12 **Q.** All right. And isn't it true that 54 minus 22 is 32?

13 **A.** Yes, sir.

14 **Q.** Thank you.

12:30:28 15 THE COURT: What happened with that case? I'm
16 not telling you to show him that case, but you had a case
17 you said you wanted to show him. I'm not telling you to do
18 it, I just didn't want --

19 MR. GORENCE: While he's getting that can I
12:30:43 20 take three seconds, Your Honor?

21 MR. DARKEN: Your Honor, there are two
22 exhibits I need to move in, VD-8 and VD-4.

23 THE COURT: Any objection to those?

24 MS. LUTZKO: No.

12:30:59 25 THE COURT: They shall be admitted.

Catizone - Recross (By Mr. Gorence)

1 Go ahead, Mr. Gorence.

2 MR. GORENCE: Your Honor, and I will be very
3 brief.

4 RECROSS EXAMINATION OF CARMEN CATIZONE

12:31:06 5 BY MR. GORENCE:

6 **Q.** Mr. Catizone, again, I'm back on the DEA notice which
7 we've looked at, and you have said that every red
8 flag -- you told this to Mr. Feran -- every red flag was hit
9 in this case.

12:31:24 10 Now, I just want to focus on the slash on the side,
11 that at least in 2001 these are the indicators that an
12 Internet pharmacy may not be legitimate, at least in the
13 eyes of DEA. First, no insurance accepted, and I'll concede
14 that Mr. Hazelwood did not take insurance.

12:31:40 15 But the next four are not applicable on the facts
16 that you have reviewed in this case. That's a true
17 statement, isn't it? You know that the software on the
18 website didn't require you to waive any rights in this case,
19 correct?

12:31:58 20 **A.** Yes, sir.

21 **Q.** You know that Hazelwood's website, USMeds, didn't say
22 that it advised about the status of the law and that it was
23 actually permissible. That red flag is not present --

24 **A.** Correct.

12:32:12 25 **Q.** -- what the DEA calls red flags. Next, the site did

Catizone - Recross (By Mr. Gorence)

1 not -- it says the site does not ask the name, address, or
2 phone number of your current physician. That actually was
3 required in this case, you had to submit medical records or
4 a medical release naming the doctor. You know that's
12:32:30 5 not -- that red flag doesn't exist here, right?

6 **A.** Yes.

7 **Q.** And then lastly, USMeds didn't advise that you had to
8 send it to some far off Post Office Box or some out of the
9 way location to avoid detection by U.S. authorities.

12:32:47 10 So at least on the five red flags the DEA thought
11 were important, four are not involved in this case. Do you
12 agree with that?

13 **A.** Yes, sir.

14 **Q.** Do you want to change your testimony about every red
12:32:58 15 flag is hit?

16 **A.** No, sir.

17 MR. GORENCE: Fair enough. That's all I have,
18 Your Honor.

19 THE COURT: All right. Mr. Feran, the time is
12:33:07 20 pretty much spent. Is there anything else?

21 MR. FERAN: Nothing on behalf of the
22 government, Your Honor.

23 THE COURT: Okay. Anything further?

24 MS. RHA: No recross, Judge.

12:33:14 25 MR. DARKEN: No, Your Honor.

1 THE COURT: All right. That will be all.

2 All right. Tuesday morning, 9:00?

3 A JUROR: Yay.

4 THE COURT: All right. Have a good weekend.

12:33:26 5 A JUROR: You, too.

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8 DIRECT EXAMINATION OF CARMEN CATIZONE 3

9 BY MR. FERAN:

10 CROSS-EXAMINATION OF CARMEN CATIZONE 90

11 BY MR. DARKEN

12 MORNING SESSION, THURSDAY, OCTOBER 11, 2012 106

13 8:40 A.M.

14 CROSS-EXAMINATION OF CARMEN CATIZONE (RESUMED) 106

15 BY MR. DARKEN

16 CROSS-EXAMINATION OF CARMEN CATIZONE 145

17 BY MR. GORENCE

18 CROSS-EXAMINATION OF CARMEN CATIZONE 172

19 BY MS. RHA

20 REDIRECT EXAMINATION OF CARMEN CATIZONE 214

21 BY MR. FERAN

22 RECROSS-EXAMINATION OF CARMEN CATIZONE 241

23 BY MR. DARKEN

24 RECROSS EXAMINATION OF CARMEN CATIZONE 247

25 BY MR. GORENCE:

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C E R T I F I C A T E

I certify that the foregoing is a correct transcript
from the record of proceedings in the above-entitled matter.

<u>s/Heidi Blueskye Geizer</u>	<u>October 27, 2012</u>
Heidi Blueskye Geizer, RMR-CRR	Date